Mexico, Distrito Federal

Mexico City, Distrito Federal, Mexico, 06800

Mexico, Jalisco

Zapopan, Jalisco, Mexico, 45060

Mexico, México

Metepec, México, Mexico, 52140

Mexico, Nuevo Leon

Monterrey, Nuevo Leon, Mexico, 64060

Monterrey, Nuevo Leon, Mexico, 64480

Mexico

Chihuahua, Mexico, 31238

Mexico City, Mexico, 06030

México D.F., Mexico, 04030

Netherlands, ZA

Leiden, ZA, Netherlands, 2333

Netherlands

Amsterdam, Netherlands, 1100 DD

Groningen, Netherlands, 9713 GZ

Nijmegen, Netherlands, 6525 EX

Rotterdam, Netherlands, 3000 CA

Poland

Bydgoszcz, Poland, 85-631

Gdansk, Poland, 80-952

Katowice, Poland, 40-760

Poznan, Poland, 61-848

Warszaa, Poland, 02-005

Warszawa, Poland, 00-416

Wroclaw, Poland, 50-368

Portugal

Coimbra, Portugal, 3000-548

Porto, Portugal, 4200-319

Singapore

Singapore, Singapore, 119074

Singapore, Singapore, 159964

Singapore, Singapore, 168751

Singapore, Singapore, 308433

Slovakia

Banska Bystrica, Slovakia, 97517

Bratislava, Slovakia, 81369

Spain, A Coruña

Santiago de Compostela, A Coruña, Spain, 15705

Spain, Asturias

Oviedo, Asturias, Spain, 33012

Spain, Navarra

Pamplona, Navarra, Spain, 31008

Spain

Alicante, Spain, 03016

Barcelona, Spain, 08017

Barcelona, Spain, 08022

Barcelona, Spain, 08035

Barcelona, Spain, 08036

Madrid, Spain, 28002

Madrid, Spain, 28046

Malaga, Spain, 29010

Sevilla, Spain, 41009

Sevilla, Spain, 41013

Valencia, Spain, 46014

Valencia, Spain, 46015

Valladolid, Spain, 47005

Sweden

Linköping, Sweden, 58185

Stockholm, Sweden, 11282

Örebro, Sweden, 70185

Switzerland

Basel, Switzerland, 4031

Bern, Switzerland, 3010

Genève, Switzerland, 1211

Zürich, Switzerland, 8091

United Kingdom, Hampshire

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Surrey

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

Aberdeen, United Kingdom, AB25 2ZN

Belfast, United Kingdom, BT12 6BA

Birmingham, United Kingdom, B4 7ET

Liverpool, United Kingdom, L7 8XP

London, United Kingdom, NW1 5QH

London, United Kingdom, SE5 9RS

Plymouth, United Kingdom, PL4 6PL

Torquay, United Kingdom, TQ2 7AA

IPDSharing

Plan to Share IPD:

References

Citations:

Links: URL: http://clinicaltrials.gov/ct2/show/NCT00509795?term=NCT00509795;rank=1

Description: Click here to view the data of the twin trial conducted by the collaboration partner.

Available IPD/Information:

Study Results

Participant Flow

Recruitment Details	The study was conducted at 186 study centers in 26 countries. Recruitment period: 21 Apr 2008 - 4 Sep 2009.
Pre-assignment Details	2031 participants were screened, 1240 were randomized and 1204 received at least 1 dose of study drug. 1204 participants were included in the Safety-Analysis Set (SAS). 1202 participants with at least 1 post-baseline measurement were included in the Full-Analysis Set (FAS).

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Overall Study

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Started	303	313	311	313
Participants Received Treatment	291 [1]	309 [1]	297 [1]	307 [1]
Participants Treated (FAS)	291	309	296	306
Completed	276	281	274	284
Not Completed	27	32	37	29
Adverse Event	2	6	8	9
Death	1	3	2	1
Lack of Efficacy	0	0	1	1
Lost to Follow-up	4	1	2	2
Protocol Violation	2	1	1	0
Withdrawal by Subject	11	15	13	11
Other (no further information available)	7	6	10	5

[1] safety population

Baseline Characteristics

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Baseline Measures

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Overall Number of Participants	291	309	296	306	1202

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Age Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		73.0 (9.0)	74.1 (8.5)	74.7 (8.6)	73.8 (8.6)	73.9 (8.7)
Sex: Female, Male [1] Measure type: Count of Participants Unit of measure: Participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
	Female	169 58.08%	176 56.96%	147 49.66%	175 57.19%	667 55.49%
	Male	122 41.92%	133 43.04%	149 50.34%	131 42.81%	535 44.51%
		[1] Measure Description: Information retrieved from all baseline participants.				
Ethnicity [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Not Hispanic or Latino		239 82.13%	259 83.82%	241 81.42%	251 82.03%	990 82.36%
Hispanic or Latino		52 17.87%	50 16.18%	55 18.58%	55 17.97%	212 17.64%
		[1] Measure Description: Information retrieved from all baseline participants.				
Race [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
White		213 73.2%	226 73.14%	219 73.99%	217 70.92%	875 72.8%
Black or African American		1 0.34%	0 0%	1 0.34%	2 0.65%	4 0.33%

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Asian		60 20.62%	67 21.68%	61 20.61%	69 22.55%	257 21.38%
Missing		17 5.84%	16 5.18%	15 5.07%	18 5.88%	66 5.49%
		[1] Measure Description: Information retrieved from all baseline participants.				
National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) total score [1]	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Mean (Standard Deviation) Unit of measure: scores on a scale		72.90 (19.09)	70.27 (19.41)	74.04 (18.22)	71.30 (19.06)	72.10 (18.99)
		[1] Measure Description: Information retrieved from 1201/1202 baseline participants. The possible range of the NEI VFQ-25 total score is between 0 (worst possible) and 100 (best possible).				
Area of Choroidal Neovascularization (CNV) [1]	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Mean (Standard Deviation) Unit of measure: mm^2		7.59 (5.34)	8.25 (5.77)	7.70 (5.26)	7.75 (5.52)	7.83 (5.48)
		[1] Measure Description: Information retrieved from 1200/1202 baseline participants.				

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Baseline lesion type [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Predominantly classic		70 24.05%	72 23.3%	80 27.03%	88 28.76%	310 25.79%
Minimally classic		104 35.74%	112 36.25%	103 34.8%	106 34.64%	425 35.36%
Occult		116 39.86%	123 39.81%	113 38.18%	110 35.95%	462 38.44%
Missing		1 0.34%	2 0.65%	0 0%	2 0.65%	5 0.42%
		[1] Measure Description: Information retrieved from 1197/1202 baseline participants.				
Baseline total lesion size [1] Mean (Standard Deviation) Unit of measure: mm^2	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		8.01 (5.74)	8.72 (6.14)	8.17 (5.51)	8.22 (5.87)	8.28 (5.82)
		[1] Measure Description: Information retrieved from 1198/1202 baseline participants.				
Best Corrected Visual Acuity (BCVA), assessed by ETDRS chart [1] Mean (Standard Deviation)	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		53.8 (13.5)	52.8 (13.9)	51.6 (14.2)	51.6 (13.9)	52.4 (13.9)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
	[1] Measure Description: Information retrieved from all baseline participants. Only participants with a ETDRS (Early Treatment Diabetic Retinopathy Study) Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye at 4 meters were included; a higher score represents better functioning.				

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)
Measure Description	Maintenance of vision was defined as a loss of < 15 letters in the ETDRS (Early Treatment Diabetic Retinopathy Study) letter score (defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning. Nominator = (Number of participants who maintained vision * 100); Denominator = Number of participants analyzed.
Time Frame	At week 52

Analysis Population Description

Per-Protocol Set (PPS); imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	269	274	268	270
Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF) Measure Type: Number Unit of Measure: Percentage of participants	94.42	95.62	96.27	95.56

Statistical Analysis 1 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 2mg Q4, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 2mg Q4).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.20
	Confidence Interval	(2-sided) 95% -4.86 to 2.46
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 2mg Q4 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

Statistical Analysis 2 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 0.5mg Q4, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 0.5mg Q4).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.84
	Confidence Interval	(2-sided) 95% -5.40 to 1.71
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 0.5mg Q4 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

Statistical Analysis 3 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 2mg Q8, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 2mg Q8).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.13
	Confidence Interval	(2-sided) 95% -4.81 to 2.55
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 2mg Q8 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

2. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning.

Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set (FAS); imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	291	309	296	306
Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: Letters correctly read	9.4 (13.5)	7.6 (12.6)	9.7 (14.1)	8.9 (14.4)

Statistical Analysis 1 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.076
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.9484
	Confidence Interval	(2-sided) 95% -4.1009 to 0.2040
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.9555
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.0620
	Confidence Interval	(2-sided) 95% -2.2398 to 2.1158
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 0.5mg Q4

Statistical Analysis 3 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4131
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.9014
	Confidence Interval	(2-sided) 95% -3.0615 to 1.2587
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q8 group

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning. Nominator = (Number of participants who maintained vision * 100); Denominator = Number of participants analyzed.
Time Frame	At week 52

Analysis Population Description

Full-Analysis Set; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	291	309	296	306
Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF Measure Type: Number Unit of Measure: Percentage of participants	34.02	29.45	34.80	31.37

Statistical Analysis 1 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.229
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-4.57
	Confidence Interval	(2-sided) 95% -12.02 to 2.88
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q4 group

Statistical Analysis 2 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.843
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	0.78
	Confidence Interval	(2-sided) 95% -6.91 to 8.46
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 0.5mg Q4 group

Statistical Analysis 3 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.490
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-2.65
	Confidence Interval	(2-sided) 95% -10.18 to 4.88
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q8 group

4. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF
Measure Description	The possible range of the NEI VFQ-25 total score is between 0 (worst possible) and 100 (best possible).
Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set with assessment for this outcome measure; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	287	304	290	299
Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: Scores on a scale	6.3 (14.8)	4.5 (15.0)	5.1 (13.7)	4.9 (14.7)

Statistical Analysis 1 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0097
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-2.7885
	Confidence Interval	(2-sided) 95% -4.9012 to -0.6757
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3917
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.9320
	Confidence Interval	(2-sided) 95% -3.0658 to 1.2019
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 0.5mg Q4.

Statistical Analysis 3 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0717
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.9470
	Confidence Interval	(2-sided) 95% -4.0659 to 0.1718
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q8.

5. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF
Measure Description	CNV area values measured in square millimeters; lower values represent better outcomes.

Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set with assessment for this outcome measure; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	278	294	287	289
Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: mm^2	-4.16 (5.90)	-5.95 (6.12)	-4.24 (6.13)	-5.16 (5.87)

Statistical Analysis 1 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0038
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.180
	Confidence Interval	(2-sided) 95% -1.979 to -0.382
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.6784
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	0.170
	Confidence Interval	(2-sided) 95% -0.632 to 0.972
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 0.5mg Q4.

Statistical Analysis 3 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0727
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.733
	Confidence Interval	(2-sided) 95% -1.534 to 0.068
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 2mg Q8.

Reported Adverse Events

Time Frame	[Not specified]
Adverse Event Reporting Description	[Not specified]

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

All-Cause Mortality

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	/	/	/	/

Serious Adverse Events

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	36/291 (12.37%)	50/309 (16.18%)	42/297 (14.14%)	50/307 (16.29%)
Blood and lymphatic system disorders				
Anaemia [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Febrile neutropenia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cardiac disorders				
Acute coronary syndrome [A*]	0/291 (0%)	2/309 (0.65%)	2/297 (0.67%)	1/307 (0.33%)
Acute myocardial infarction [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Angina pectoris [A*]	1/291 (0.34%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Arteriosclerosis coronary artery [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Atrial fibrillation [A*]	2/291 (0.69%)	1/309 (0.32%)	0/297 (0%)	3/307 (0.98%)
Atrial flutter [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Atrioventricular block [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cardiac arrest [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cardiac failure [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cardiopulmonary failure [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cardiovascular insufficiency [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Coronary artery disease [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Myocardial infarction [A*]	2/291 (0.69%)	1/309 (0.32%)	3/297 (1.01%)	3/307 (0.98%)
Myocardial ischaemia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Palpitations [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Pericarditis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Supraventricular tachycardia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Ear and labyrinth disorders				
Tympanic membrane disorder [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Vertigo [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Eye disorders				
Cataract (Fellow Eye) [A*]	3/291 (1.03%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Cataract (Study Eye) [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Cataract cortical (Study Eye) [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cataract nuclear (Study Eye) [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Choroidal detachment (Study Eye) [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Choroidal neovascularisation (Fellow Eye) [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Hyphaema (Study Eye) [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Macular cyst (Study Eye) [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Macular degeneration (Fellow Eye) [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	1/307 (0.33%)
Macular degeneration (Study Eye) [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Macular hole (Study Eye) [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Maculopathy (Fellow Eye) [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Posterior capsule opacification (Study Eye) [A*]	2/291 (0.69%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Retinal degeneration (Study Eye) [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Retinal detachment (Study Eye) [A*]	1/291 (0.34%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Retinal haemorrhage (Fellow Eye) [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Retinal haemorrhage (Study Eye) [A*]	1/291 (0.34%)	2/309 (0.65%)	1/297 (0.34%)	1/307 (0.33%)
Retinal pigment epithelial tear (Study Eye) [A*]	1/291 (0.34%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Retinal pigment epitheliopathy (Fellow Eye) [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Retinal pigment epitheliopathy (Study Eye) [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Retinal vein occlusion (Fellow Eye) [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Visual acuity reduced (Fellow Eye) [A*]	0/291 (0%)	3/309 (0.97%)	0/297 (0%)	1/307 (0.33%)
Visual acuity reduced (Study Eye) [A*]	2/291 (0.69%)	1/309 (0.32%)	1/297 (0.34%)	5/307 (1.63%)
Vitreous haemorrhage (Fellow Eye) [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Gastrointestinal disorders				
Anal fistula [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Colitis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Constipation [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Diverticulum intestinal [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gastric ulcer [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Gastritis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Gastritis erosive [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Inguinal hernia [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Intestinal obstruction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Large intestine perforation [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lower gastrointestinal haemorrhage [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Pancreatitis acute [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Small intestinal obstruction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
General disorders				
Chest pain [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Death [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Device dislocation [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Device malfunction [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Oedema peripheral [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Pyrexia [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	0/307 (0%)
Hepatobiliary disorders				
Cholecystitis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cholecystitis acute [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cholelithiasis [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Infections and infestations				
Appendicitis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Bronchitis [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Dysentery [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Escherichia sepsis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gastroenteritis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gastroenteritis norovirus [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Gastroenteritis salmonella [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Pneumonia [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	2/307 (0.65%)
Pneumonia pneumococcal [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Postoperative wound infection [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Respiratory tract infection [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Septic shock [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Urinary tract infection [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Injury, poisoning and procedural complications				
Accident [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Ankle fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Burns second degree [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Clavicle fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Concussion [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Contusion [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Fall [A*]	2/291 (0.69%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Femoral neck fracture [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Femur fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Graft thrombosis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Head injury [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Injury [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Joint injury [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Lower limb fracture [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Lumbar vertebral fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Macular scar [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Meniscus lesion [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Post procedural complication [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Radius fracture [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Road traffic accident [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Skull fractured base [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Subdural haematoma [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Upper limb fracture [A*]	0/291 (0%)	0/309 (0%)	2/297 (0.67%)	0/307 (0%)
Wound haemorrhage [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Investigations				
Blood osmolarity decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Electrocardiogram QT prolonged [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Intraocular pressure increased [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Metabolism and nutrition disorders				
Dehydration [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Diabetes mellitus [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hyperglycaemia [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Arthritis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Dupuytren's contracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Intervertebral disc protrusion [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Neck pain [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Rheumatoid arthritis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Sjogren's syndrome [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Synovitis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Acute myeloid leukaemia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Basal cell carcinoma [A*]	1/291 (0.34%)	0/309 (0%)	2/297 (0.67%)	0/307 (0%)
Bladder cancer [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bladder cancer recurrent [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Breast cancer [A*]	1/291 (0.34%)	0/309 (0%)	3/297 (1.01%)	1/307 (0.33%)
Colon cancer [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colon cancer metastatic [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Lung cancer metastatic [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lung carcinoma cell type unspecified stage IV [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Lung neoplasm malignant [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Oesophageal carcinoma [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Ovarian cancer [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Prostate cancer metastatic [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Squamous cell carcinoma [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Nervous system disorders				
Brain oedema [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cerebral infarction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cerebrovascular accident [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	2/307 (0.65%)
Epilepsy [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Headache [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Hypertensive encephalopathy [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lacunar infarction [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nerve root compression [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Petit mal epilepsy [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Syncope [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Transient ischaemic attack [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	0/307 (0%)
VIIth nerve paralysis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Psychiatric disorders				
Depression [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Renal and urinary disorders				
Renal failure [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Urinary tract obstruction [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Reproductive system and breast disorders				
Benign prostatic hyperplasia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Uterine haemorrhage [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Respiratory, thoracic and mediastinal disorders				
Acute pulmonary oedema [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Chronic obstructive pulmonary disease [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Cough [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Dyspnoea [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Pleurisy [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Pneumothorax [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Sleep apnoea syndrome [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Skin and subcutaneous tissue disorders				

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Dermal cyst [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Dermatitis allergic [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Erythema multiforme [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Rash [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Skin necrosis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Skin ulcer [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Surgical and medical procedures				
Blepharoplasty [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cataract operation [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Haematoma evacuation [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hip surgery [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Strangulated hernia repair [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Vaginal operation [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Vascular disorders				
Circulatory collapse [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Haematoma [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hypertension [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Hypertensive crisis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Peripheral artery aneurysm A*	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Varicose vein A*	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA (13.1)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	208/291 (71.48%)	209/309 (67.64%)	209/297 (70.37%)	217/307 (70.68%)
Cardiac disorders				
Atrioventricular block first degree A*	12/291 (4.12%)	22/309 (7.12%)	18/297 (6.06%)	17/307 (5.54%)
Eye disorders				
Cataract (Study Eye) A*	14/291 (4.81%)	17/309 (5.5%)	12/297 (4.04%)	13/307 (4.23%)
Choroidal neovascularisation (Fellow Eye) A*	14/291 (4.81%)	14/309 (4.53%)	15/297 (5.05%)	17/307 (5.54%)
Conjunctival haemorrhage (Study Eye) A*	23/291 (7.9%)	24/309 (7.77%)	37/297 (12.46%)	30/307 (9.77%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Detachment of retinal pigment epithelium (Study Eye) [A*]	26/291 (8.93%)	26/309 (8.41%)	24/297 (8.08%)	25/307 (8.14%)
Eye pain (Study Eye) [A*]	27/291 (9.28%)	33/309 (10.68%)	22/297 (7.41%)	21/307 (6.84%)
Macular cyst (Study Eye) [A*]	15/291 (5.15%)	6/309 (1.94%)	7/297 (2.36%)	6/307 (1.95%)
Macular degeneration (Fellow Eye) [A*]	18/291 (6.19%)	17/309 (5.5%)	25/297 (8.42%)	33/307 (10.75%)
Macular degeneration (Study Eye) [A*]	27/291 (9.28%)	28/309 (9.06%)	27/297 (9.09%)	33/307 (10.75%)
Ocular hyperaemia (Study Eye) [A*]	18/291 (6.19%)	13/309 (4.21%)	13/297 (4.38%)	9/307 (2.93%)
Retinal cyst (Study Eye) [A*]	10/291 (3.44%)	16/309 (5.18%)	14/297 (4.71%)	11/307 (3.58%)
Retinal degeneration (Study Eye) [A*]	23/291 (7.9%)	27/309 (8.74%)	20/297 (6.73%)	18/307 (5.86%)
Retinal haemorrhage (Fellow Eye) [A*]	21/291 (7.22%)	17/309 (5.5%)	12/297 (4.04%)	21/307 (6.84%)
Retinal haemorrhage (Study Eye) [A*]	39/291 (13.4%)	41/309 (13.27%)	39/297 (13.13%)	37/307 (12.05%)
Retinal oedema (Study Eye) [A*]	18/291 (6.19%)	17/309 (5.5%)	14/297 (4.71%)	23/307 (7.49%)
Retinal pigment epitheliopathy (Study Eye) [A*]	25/291 (8.59%)	22/309 (7.12%)	19/297 (6.4%)	24/307 (7.82%)
Visual acuity reduced (Fellow Eye) [A*]	10/291 (3.44%)	10/309 (3.24%)	13/297 (4.38%)	19/307 (6.19%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Visual acuity reduced (Study Eye) A*	19/291 (6.53%)	25/309 (8.09%)	33/297 (11.11%)	30/307 (9.77%)
Vitreous detachment (Study Eye) A*	10/291 (3.44%)	19/309 (6.15%)	10/297 (3.37%)	15/307 (4.89%)
General disorders				
Pyrexia A*	9/291 (3.09%)	7/309 (2.27%)	15/297 (5.05%)	5/307 (1.63%)
Infections and infestations				
Influenza A*	8/291 (2.75%)	14/309 (4.53%)	8/297 (2.69%)	17/307 (5.54%)
Nasopharyngitis A*	28/291 (9.62%)	15/309 (4.85%)	26/297 (8.75%)	19/307 (6.19%)
Investigations				
Intraocular pressure increased A*	23/291 (7.9%)	30/309 (9.71%)	21/297 (7.07%)	22/307 (7.17%)
Nervous system disorders				
Headache A*	12/291 (4.12%)	9/309 (2.91%)	12/297 (4.04%)	17/307 (5.54%)
Vascular disorders				
Hypertension A*	25/291 (8.59%)	22/309 (7.12%)	19/297 (6.4%)	19/307 (6.19%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA (13.1)

Limitations and Caveats

The conditional sequence of hypothesis testing had to stop after testing the first superiority hypothesis. Therefore, all further statistical tests are exploratory tests.

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Official Title: Therapeutic Area Head
Organization: BAYER
Phone:
Email: clinical-trials-contact@bayerhealthcare.com

Scroll up to access the controls Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	◉	◉	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: June 6, 2011 (v25)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD)

Secondary IDs: EudraCT: 2007-000583-25

Study Status

Record Verification: June 2011

Overall Status: Active, not recruiting

Study Start: April 2008

Primary Completion: September 2010 [Actual]

Study Completion: August 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: June 6, 2011

Last Update Posted: June 7, 2011 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators: Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1240 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Regeneron Ex. 2001
Fresenius v. Regeneron
IPR2025-01269
Page 2055 of 3000

Arms	Assigned Interventions
Experimental: Arm 3	Biological: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Biological: VEGF Trap-Eye (BAY86-5321) 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Biological: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in Best Corrected Visual Acuity (BCVA) as measured by ETDRS (Early Treatment Diabetic Retinopathy Study) letter score at Week 52

Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 (National Eye Institute Visual Functioning Questionaire) score at Week 52
   Week 52
5. Mean change from baseline in CNV (Choroidal Neovascularization) area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.
- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Ciudad Auton. de Buenos Aires**

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1015ABO

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1023AAQ

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1122AAI

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1181ACH

Argentina, Santa Fe

Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

Córdoba, Argentina, X5000IIT

Australia, New South Wales

Chatswood, New South Wales, Australia, 2067

Sydney, New South Wales, Australia, 2000

Westmead, New South Wales, Australia, 2145

Australia, Victoria

East Melbourne, Victoria, Australia, 3002

Parkville, Victoria, Australia, 3050

Australia, Western Australia

Nedlands, Western Australia, Australia, 6009

Australia

Parramatta, Australia, 2150

Austria

Innsbruck, Austria, 6020

Linz, Austria, 4021

Wien, Austria, 1090

Belgium

Liege, Belgium, 4000

Brazil, Sao Paulo

Ribeirão Preto, Sao Paulo, Brazil, 14048-900

São Paulo, Sao Paulo, Brazil, 05651-901

Brazil

Minas Gerais, Brazil, 30150-270

Sao Paulo, Brazil, 04023-062

Colombia, Antioquia

Medellín, Antioquia, Colombia

Colombia, Cauca

Cali, Cauca, Colombia

Colombia, Distrito Capital de Bogotá

Bogota, Distrito Capital de Bogotá, Colombia

Czech Republic

Brno, Czech Republic, 63400

Olonouc, Czech Republic, 77520

Praha 10, Czech Republic, 10034

Praha 4, Czech Republic, 14000

Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

Paris, Cedex 12, France, 75557

France, Cedex 1

Nantes, Cedex 1, France, 44093

France

Besancon, France, 25030

Bordeaux, France, 33000

Dijon, France, 21079

Lyon, France, 69003

Lyon, France, 69006

Marseille, France, 13008

Paris, France, 75010

Paris, France, 75015

Germany, Baden-Württemberg

Freiburg, Baden-Württemberg, Germany, 79106

Heidelberg, Baden-Württemberg, Germany, 69120

Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

München, Bayern, Germany, 81675

Regensburg, Bayern, Germany, 93053

Germany, Hessen

Darmstadt, Hessen, Germany, 64297

Germany, Nordrhein-Westfalen

Aachen, Nordrhein-Westfalen, Germany, 52074

Bonn, Nordrhein-Westfalen, Germany, 53105

Essen, Nordrhein-Westfalen, Germany, 45122

Köln, Nordrhein-Westfalen, Germany, 50924

Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

Ludwigshafen, Rheinland-Pfalz, Germany, 67063

Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

Homburg, Saarland, Germany, 66421

Germany, Sachsen

Dresden, Sachsen, Germany, 01307

Dresden, Sachsen, Germany, 06067

Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

Kiel, Schleswig-Holstein, Germany, 24105

Lübeck, Schleswig-Holstein, Germany, 23538

Germany

Berlin, Germany, 12200

Hamburg, Germany, 20251

Hungary

Budapest, Hungary, 1083

Budapest, Hungary, 1106

Budapest, Hungary, 1133

Veszprem, Hungary, 8200

India, Gujrat

Ahemedabad - 4, Gujrat, India, 380009

India, Maharashtra

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil N?du

Chennai, Tamil N?du, India, 600 006

Coimbatore, Tamil N?du, India, 641014

Madurai, Tamil N?du, India, 625 020

Pondicherry, Tamil N?du, India, 600007

India

Bangalore, India, 560010

Chandigarh, India, 160012

Hyderabad, India, 500 034

Kerala, India, 683572

Kolkata, India, 700073

Mumbai, India, 400 050

New Delhi, India, 110002

New Delhi, India, 110029

Orissa, India, 751 024

Israel

Afula, Israel

Beer Sheva, Israel

Haifa, Israel, 34362

Jerusalem, Israel, 91120

Kfar Saba, Israel

Petach Tikva, Israel, 49100

Rehovot, Israel, 76100

Tel Aviv, Israel, 64239

Tel Hashomer, Israel

Zrifin, Israel, 70300

Italy

Ancona, Italy, 60126

Bari, Italy, 70124

Catania, Italy, 95123

Genova, Italy, 16132

Milano, Italy, 20122

Milano, Italy, 20132

Milano, Italy, 20157

Padova, Italy, 35128

Roma, Italy, 00133

Roma, Italy, 00168

Roma, Italy, 00198

Torino, Italy, 10122

Udine, Italy, 33100

Varese, Italy, 21100

Verona, Italy, 37121

Japan, Aichi

Nagoya, Aichi, Japan, 466-8560

Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

Kita, Kagawa, Japan, 761-0793

Japan, Osaka

Hirakata, Osaka, Japan, 573-1191

Suita, Osaka, Japan, 565-0871

Japan, Shiga

Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

Chiyoda-ku, Tokyo, Japan, 101-8309

Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

Fukuoka, Japan, 812-8582

Fukushima, Japan, 960-1295

Kagoshima, Japan, 890-8520

Kyoto, Japan, 606-8507

Korea, Republic of, Gyeonggido

Seongnam, Gyeonggido, Korea, Republic of, 463 707

Korea, Republic of

Incheon, Korea, Republic of, 405-760

Seoul, Korea, Republic of, 110 744

Seoul, Korea, Republic of, 137 701

Seoul, Korea, Republic of, 138-736

Seoul, Korea, Republic of, 152-703

Latvia

Riga, Latvia, 1002

Riga, Latvia, 1009

Riga, Latvia, 1050

Mexico, Distrito Federal

Mexico City, Distrito Federal, Mexico, 06800

Mexico, Jalisco

Zapopan, Jalisco, Mexico, 45060

Mexico, México

Metepec, México, Mexico, 52140

Mexico, Nuevo Leon

Monterrey, Nuevo Leon, Mexico, 64060

Monterrey, Nuevo Leon, Mexico, 64480

Mexico

Chihuahua, Mexico, 31238

Mexico City, Mexico, 06030

México D.F., Mexico, 04030

Netherlands, ZA

Leiden, ZA, Netherlands, 2333

Netherlands

Amsterdam, Netherlands, 1100 DD

Groningen, Netherlands, 9713 GZ

Nijmegen, Netherlands, 6525 EX

Rotterdam, Netherlands, 3000 CA

Poland

Bydgoszcz, Poland, 85-631

Gdansk, Poland, 80-952

Katowice, Poland, 40-760

Poznan, Poland, 61-848

Warszaa, Poland, 02-005

Warszawa, Poland, 00-416

Wroclaw, Poland, 50-368

Portugal

Coimbra, Portugal, 3000-548

Porto, Portugal, 4200-319

Singapore

Singapore, Singapore, 119074

Singapore, Singapore, 159964

Singapore, Singapore, 168751

Singapore, Singapore, 308433

Slovakia

Banska Bystrica, Slovakia, 97517

Bratislava, Slovakia, 81369

Spain, A Coruña

Santiago de Compostela, A Coruña, Spain, 15705

Spain, Asturias

Oviedo, Asturias, Spain, 33012

Spain, Navarra

Pamplona, Navarra, Spain, 31008

Spain

Alicante, Spain, 03016

Barcelona, Spain, 08017

Barcelona, Spain, 08022

Barcelona, Spain, 08035

Barcelona, Spain, 08036

Madrid, Spain, 28002

Madrid, Spain, 28046

Malaga, Spain, 29010

Sevilla, Spain, 41009

Sevilla, Spain, 41013

Valencia, Spain, 46014

Valencia, Spain, 46015

Valladolid, Spain, 47005

Sweden

Linköping, Sweden, 58185

Stockholm, Sweden, 11282

Örebro, Sweden, 70185

Switzerland

Basel, Switzerland, 4031

Bern, Switzerland, 3010

Genève, Switzerland, 1211

Zürich, Switzerland, 8091

United Kingdom, Hampshire

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Surrey

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

Aberdeen, United Kingdom, AB25 2ZN

Belfast, United Kingdom, BT12 6BA

Birmingham, United Kingdom, B4 7ET

Liverpool, United Kingdom, L7 8XP

London, United Kingdom, NW1 5QH

London, United Kingdom, SE5 9RS

Plymouth, United Kingdom, PL4 6PL

Torquay, United Kingdom, TQ2 7AA

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	◉	◉	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: May 23, 2011 (v24)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD)

Secondary IDs: EudraCT: 2007-000583-25

Study Status

Record Verification: May 2011

Overall Status: Active, not recruiting

Study Start: April 2008

Primary Completion: September 2010 [Actual]

Study Completion: August 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: May 23, 2011

Last Update Posted: May 24, 2011 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators: Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1240 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye (BAY86-5321) 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Ciudad Auton. de Buenos Aires**

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1015ABO

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1023AAQ

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1122AAI

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1181ACH

Argentina, Santa Fe

Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

Córdoba, Argentina, X5000IIT

Australia, New South Wales

Chatswood, New South Wales, Australia, 2067

Sydney, New South Wales, Australia, 2000

Westmead, New South Wales, Australia, 2145

Australia, Victoria

East Melbourne, Victoria, Australia, 3002

Parkville, Victoria, Australia, 3050

Australia, Western Australia

Nedlands, Western Australia, Australia, 6009

Australia

Parramatta, Australia, 2150

Austria

Innsbruck, Austria, 6020

Linz, Austria, 4021

Wien, Austria, 1090

Belgium

Liege, Belgium, 4000

Brazil, Sao Paulo

Ribeirão Preto, Sao Paulo, Brazil, 14048-900

São Paulo, Sao Paulo, Brazil, 05651-901

Brazil

Minas Gerais, Brazil, 30150-270

Sao Paulo, Brazil, 04023-062

Colombia, Antioquia

Medellín, Antioquia, Colombia

Colombia

Bogota, Colombia

Cali, Colombia

Medellín, Colombia

Czech Republic

Brno, Czech Republic, 63400

Olonouc, Czech Republic, 77520

Praha 10, Czech Republic, 10034

Praha 4, Czech Republic, 14000

Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

Paris, Cedex 12, France, 75557

France, Cedex 1

Nantes, Cedex 1, France, 44093

France

Besancon, France, 25030

Bordeaux, France, 33000

Dijon, France, 21079

Lyon, France, 69003

Lyon, France, 69006

Marseille, France, 13008

Paris, France, 75010

Paris, France, 75015

Germany, Baden-Württemberg

Freiburg, Baden-Württemberg, Germany, 79106

Heidelberg, Baden-Württemberg, Germany, 69120

Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

München, Bayern, Germany, 81675

Regensburg, Bayern, Germany, 93053

Germany, Hessen

Darmstadt, Hessen, Germany, 64297

Germany, Nordrhein-Westfalen

Aachen, Nordrhein-Westfalen, Germany, 52074

Bonn, Nordrhein-Westfalen, Germany, 53105

Essen, Nordrhein-Westfalen, Germany, 45122

Köln, Nordrhein-Westfalen, Germany, 50924

Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

Ludwigshafen, Rheinland-Pfalz, Germany, 67063

Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

Homburg, Saarland, Germany, 66421

Germany, Sachsen

Dresden, Sachsen, Germany, 01307

Dresden, Sachsen, Germany, 06067

Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

Kiel, Schleswig-Holstein, Germany, 24105

Lübeck, Schleswig-Holstein, Germany, 23538

Germany

Berlin, Germany, 12200

Hamburg, Germany, 20251

Hungary

Budapest, Hungary, 1083

Budapest, Hungary, 1106

Budapest, Hungary, 1133

Veszprem, Hungary, 8200

India, Gujrat

Ahemedabad - 4, Gujrat, India, 380009

India, Maharashtra

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil N?du

Chennai, Tamil N?du, India, 600 006

Coimbatore, Tamil N?du, India, 641014

Madurai, Tamil N?du, India, 625 020

Pondicherry, Tamil N?du, India, 600007

India

Bangalore, India, 560010

Chandigarh, India, 160012

Hyderabad, India, 500 034

Kerala, India, 683572

Kolkata, India, 700073

Mumbai, India, 400 050

New Delhi, India, 110002

New Delhi, India, 110029

Orissa, India, 751 024

Israel

Afula, Israel

Beer Sheva, Israel

Haifa, Israel, 34362

Jerusalem, Israel, 91120

Kfar Saba, Israel

Petach Tikva, Israel, 49100

Rehovot, Israel, 76100

Tel Aviv, Israel, 64239

Tel Hashomer, Israel

Zrifin, Israel, 70300

Italy

Ancona, Italy, 60126

Bari, Italy, 70124

Catania, Italy, 95123

Genova, Italy, 16132

Milano, Italy, 20122

Milano, Italy, 20132

Milano, Italy, 20157

Padova, Italy, 35128

Roma, Italy, 00133

Roma, Italy, 00168

Roma, Italy, 00198

Torino, Italy, 10122

Udine, Italy, 33100

Varese, Italy, 21100

Verona, Italy, 37121

Japan, Aichi

Nagoya, Aichi, Japan, 466-8560

Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

Kita, Kagawa, Japan, 761-0793

Japan, Osaka

Hirakata, Osaka, Japan, 573-1191

Suita, Osaka, Japan, 565-0871

Japan, Shiga

Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

Chiyoda-ku, Tokyo, Japan, 101-8309

Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

Fukuoka, Japan, 812-8582

Fukushima, Japan, 960-1295

Kagoshima, Japan, 890-8520

Kyoto, Japan, 606-8507

Korea, Republic of, Gyeonggido

Seongnam, Gyeonggido, Korea, Republic of, 463 707

Korea, Republic of

Incheon, Korea, Republic of, 405-760

Seoul, Korea, Republic of, 110 744

Seoul, Korea, Republic of, 137 701

Seoul, Korea, Republic of, 138-736

Seoul, Korea, Republic of, 152-703

Latvia

Riga, Latvia, 1002

Riga, Latvia, 1009

Riga, Latvia, 1050

Mexico, Distrito Federal

Mexico City, Distrito Federal, Mexico, 06800

Mexico, Jalisco

Zapopan, Jalisco, Mexico, 45060

Mexico, México

Metepec, México, Mexico, 52140

Mexico, Nuevo Leon

Monterrey, Nuevo Leon, Mexico, 64060

Monterrey, Nuevo Leon, Mexico, 64480

Mexico

Chihuahua, Mexico, 31238

Mexico City, Mexico, 06030

México D.F., Mexico, 04030

Netherlands, ZA

Leiden, ZA, Netherlands, 2333

Netherlands

Amsterdam, Netherlands, 1100 DD

Groningen, Netherlands, 9713 GZ

Nijmegen, Netherlands, 6525 EX

Rotterdam, Netherlands, 3000 CA

Poland

Bydgoszcz, Poland, 85-631

Gdansk, Poland, 80-952

Katowice, Poland, 40-760

Poznan, Poland, 61-848

Warszaa, Poland, 02-005

Warszawa, Poland, 00-416

Wroclaw, Poland, 50-368

Portugal

Coimbra, Portugal, 3000-548

Porto, Portugal, 4200-319

Singapore

Singapore, Singapore, 119074

Singapore, Singapore, 159964

Singapore, Singapore, 168751

Singapore, Singapore, 308433

Slovakia

Banska Bystrica, Slovakia, 97517

Bratislava, Slovakia, 81369

Spain, A Coruña

Santiago de Compostela, A Coruña, Spain, 15705

Spain, Asturias

Oviedo, Asturias, Spain, 33012

Spain, Navarra

Pamplona, Navarra, Spain, 31008

Spain

Alicante, Spain, 03016

Barcelona, Spain, 08017

Barcelona, Spain, 08022

Barcelona, Spain, 08035

Barcelona, Spain, 08036

Madrid, Spain, 28002

Madrid, Spain, 28046

Malaga, Spain, 29010

Sevilla, Spain, 41009

Sevilla, Spain, 41013

Valencia, Spain, 46014

Valencia, Spain, 46015

Valladolid, Spain, 47005

Sweden

Linköping, Sweden, 58185

Stockholm, Sweden, 11282

Örebro, Sweden, 70185

Switzerland

Basel, Switzerland, 4031

Bern, Switzerland, 3010

Genève, Switzerland, 1211

Zürich, Switzerland, 8091

United Kingdom, Hampshire

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Surrey

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

Aberdeen, United Kingdom, AB25 2ZN

Belfast, United Kingdom, BT12 6BA

Birmingham, United Kingdom, B4 7ET

Liverpool, United Kingdom, L7 8XP

London, United Kingdom, NW1 5QH

London, United Kingdom, SE5 9RS

Plymouth, United Kingdom, PL4 6PL

Torquay, United Kingdom, TQ2 7AA

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	◉	◉	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: February 21, 2011 (v23)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

	Related Macular Degeneration (AMD) (VIEW 2)
Official Title:	A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD)
Secondary IDs:	EurdaCT No.: 2007-000583-25

Study Status

Record Verification:	February 2011
Overall Status:	Active, not recruiting
Study Start:	April 2008
Primary Completion:	September 2010 [Actual]
Study Completion:	August 2011 [Anticipated]
First Submitted:	March 12, 2008
First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	February 21, 2011
Last Update Posted:	February 23, 2011 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1240 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye (BAY86-5321) 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Ciudad Auton. de Buenos Aires**

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1015ABO

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1023AAQ

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1122AAI

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1181ACH

Argentina, Santa Fe

Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

Córdoba, Argentina, X5000IIT

Australia, New South Wales

Chatswood, New South Wales, Australia, 2067

Sydney, New South Wales, Australia, 2000

Westmead, New South Wales, Australia, 2145

Australia, Victoria

East Melbourne, Victoria, Australia, 3002

Parkville, Victoria, Australia, 3050

Australia, Western Australia

Nedlands, Western Australia, Australia, 6009

Australia

Parramatta, Australia, 2150

Austria

Innsbruck, Austria, 6020

Linz, Austria, 4021

Wien, Austria, 1090

Belgium

Liege, Belgium, 4000

Brazil, Sao Paulo

Ribeirão Preto, Sao Paulo, Brazil, 14048-900

São Paulo, Sao Paulo, Brazil, 05651-901

Brazil

Minas Gerais, Brazil, 30150-270

Sao Paulo, Brazil, 04023-062

Colombia, Antioquia

Medellín, Antioquia, Colombia

Colombia

Bogota, Colombia

Cali, Colombia

Medellín, Colombia

Czech Republic

Brno, Czech Republic, 63400

Olonouc, Czech Republic, 77520

Praha 10, Czech Republic, 10034

Praha 4, Czech Republic, 14000

Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

Paris, Cedex 12, France, 75557

France, Cedex 1

Nantes, Cedex 1, France, 44093

France

Besancon, France, 25030

Bordeaux, France, 33000

Dijon, France, 21079

Lyon, France, 69003

Lyon, France, 69006

Marseille, France, 13008

Paris, France, 75010

Paris, France, 75015

Germany, Baden-Württemberg

Freiburg, Baden-Württemberg, Germany, 79106

Heidelberg, Baden-Württemberg, Germany, 69120

Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

München, Bayern, Germany, 81675

Regensburg, Bayern, Germany, 93053

Germany, Hessen

Darmstadt, Hessen, Germany, 64297

Germany, Nordrhein-Westfalen

Aachen, Nordrhein-Westfalen, Germany, 52074

Bonn, Nordrhein-Westfalen, Germany, 53105

Essen, Nordrhein-Westfalen, Germany, 45122

Köln, Nordrhein-Westfalen, Germany, 50924

Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

Ludwigshafen, Rheinland-Pfalz, Germany, 67063

Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

Homburg, Saarland, Germany, 66424

Germany, Sachsen

Dresden, Sachsen, Germany, 01307

Dresden, Sachsen, Germany, 06067

Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

Kiel, Schleswig-Holstein, Germany, 24105

Lübeck, Schleswig-Holstein, Germany, 23538

Germany

Berlin, Germany, 12200

Hamburg, Germany, 20251

Hungary

Budapest, Hungary, 1083

Budapest, Hungary, 1106

Budapest, Hungary, 1133

Veszprem, Hungary, 8200

India, Gujrat

Ahemedabad - 4, Gujrat, India, 380009

India, Maharashtra

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil N?du

Chennai, Tamil N?du, India, 600 006

Coimbatore, Tamil N?du, India, 641014

Madurai, Tamil N?du, India, 625 020

Pondicherry, Tamil N?du, India, 600007

India

Bangalore, India, 560010

Chandigarh, India, 160012

Hyderabad, India, 500 034

Kerala, India, 683572

Kolkata, India, 700073

Mumbai, India, 400 050

New Delhi, India, 110002

New Delhi, India, 110029

Orissa, India, 751 024

Israel

Afula, Israel

Beer Sheva, Israel

Haifa, Israel, 34362

Jerusalem, Israel, 91120

Kfar Saba, Israel

Petach Tikva, Israel, 49100

Rehovot, Israel, 76100

Tel Aviv, Israel, 64239

Tel Hashomer, Israel

Zrifin, Israel, 70300

Italy

Ancona, Italy, 60126

Bari, Italy, 70124

Catania, Italy, 95123

Genova, Italy, 16132

Milano, Italy, 20122

Milano, Italy, 20132

Milano, Italy, 20157

Padova, Italy, 35128

Roma, Italy, 00133

Roma, Italy, 00168

Roma, Italy, 00198

Torino, Italy, 10122

Udine, Italy, 33100

Varese, Italy, 21100

Verona, Italy, 37121

Japan, Aichi

Nagoya, Aichi, Japan, 466-8560

Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

Kita, Kagawa, Japan, 761-0793

Japan, Osaka

Hirakata, Osaka, Japan, 573-1191

Suita, Osaka, Japan, 565-0871

Japan, Shiga

Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

Chiyoda-ku, Tokyo, Japan, 101-8309

Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

Fukuoka, Japan, 812-8582

Fukushima, Japan, 960-1295

Kagoshima, Japan, 890-8520

Kyoto, Japan, 606-8507

Korea, Republic of, Gyeonggido

Seongnam, Gyeonggido, Korea, Republic of, 463 707

Korea, Republic of

Incheon, Korea, Republic of, 405-760

Seoul, Korea, Republic of, 110 744

Seoul, Korea, Republic of, 137 701

Seoul, Korea, Republic of, 138-736

Seoul, Korea, Republic of, 152-703

Latvia

Riga, Latvia, 1002

Riga, Latvia, 1009

Riga, Latvia, 1050

Mexico, Distrito Federal

Mexico City, Distrito Federal, Mexico, 06800

Mexico, Jalisco

Zapopan, Jalisco, Mexico, 45060

Mexico, México

Metepec, México, Mexico, 52140

Mexico, Nuevo Leon

Monterrey, Nuevo Leon, Mexico, 64060

Monterrey, Nuevo Leon, Mexico, 64480

Mexico

Chihuahua, Mexico, 31238

Mexico City, Mexico, 06030

México D.F., Mexico, 04030

Netherlands, ZA

Leiden, ZA, Netherlands, 2333

Netherlands

Amsterdam, Netherlands, 1100 DD

Groningen, Netherlands, 9713 GZ

Nijmegen, Netherlands, 6525 EX

Rotterdam, Netherlands, 3000 CA

Poland

Bydgoszcz, Poland, 85-631

Gdansk, Poland, 80-952

Katowice, Poland, 40-760

Poznan, Poland, 61-848

Warszaa, Poland, 02-005

Warszawa, Poland, 00-416

Wroclaw, Poland, 50-368

Portugal

Coimbra, Portugal, 3000-548

Porto, Portugal, 4200-319

Singapore

Singapore, Singapore, 119074

Singapore, Singapore, 159964

Singapore, Singapore, 168751

Singapore, Singapore, 308433

Slovakia

Banska Bystrica, Slovakia, 97517

Bratislava, Slovakia, 81369

Spain, A Coruña

Santiago de Compostela, A Coruña, Spain, 15705

Spain, Asturias

Oviedo, Asturias, Spain, 33012

Spain, Navarra

Pamplona, Navarra, Spain, 31008

Spain

Alicante, Spain, 03016

Barcelona, Spain, 08017

Barcelona, Spain, 08022

Barcelona, Spain, 08035

Barcelona, Spain, 08036

Madrid, Spain, 28002

Madrid, Spain, 28046

Malaga, Spain, 29010

Sevilla, Spain, 41009

Sevilla, Spain, 41013

Valencia, Spain, 46014

Valencia, Spain, 46015

Valladolid, Spain, 47005

Sweden

Linköping, Sweden, 58185

Stockholm, Sweden, 11282

Örebro, Sweden, 70185

Switzerland

Basel, Switzerland, 4031

Bern, Switzerland, 3010

Genève, Switzerland, 1211

Zürich, Switzerland, 8091

United Kingdom, Hampshire

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Surrey

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

Aberdeen, United Kingdom, AB25 2ZN

Belfast, United Kingdom, BT12 6BA

Birmingham, United Kingdom, B4 7ET

Liverpool, United Kingdom, L7 8XP

London, United Kingdom, NW1 5QH

London, United Kingdom, SE5 9RS

Plymouth, United Kingdom, PL4 6PL

Torquay, United Kingdom, TQ2 7AA

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	◉	◉	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: November 30, 2010 (v22)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD)

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification: November 2010

Overall Status: Active, not recruiting

Study Start: April 2008

Primary Completion: September 2010 [Actual]

Study Completion: August 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: November 30, 2010

Last Update Posted: December 1, 2010 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1240 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye (BAY86-5321) 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Ciudad Auton. de Buenos Aires**

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1015ABO

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1023AAQ

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1122AAI

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1181ACH

Argentina, Santa Fe

Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

Córdoba, Argentina, X5000IIT

Australia, New South Wales

Chatswood, New South Wales, Australia, 2067

Sydney, New South Wales, Australia, 2000

Westmead, New South Wales, Australia, 2145

Australia, Victoria

East Melbourne, Victoria, Australia, 3002

Parkville, Victoria, Australia, 3050

Australia, Western Australia

Nedlands, Western Australia, Australia, 6009

Australia

Parramatta, Australia, 2150

Austria

Innsbruck, Austria, 6020

Linz, Austria, 4021

Wien, Austria, 1090

Belgium

Liege, Belgium, 4000

Brazil, Sao Paulo

Ribeirão Preto, Sao Paulo, Brazil, 14048-900

São Paulo, Sao Paulo, Brazil, 05651-901

Brazil

Minas Gerais, Brazil, 30150-270

Sao Paulo, Brazil, 04023-062

Colombia, Antioquia

Medellín, Antioquia, Colombia

Colombia

Bogota, Colombia

Cali, Colombia

Medellín, Colombia

Czech Republic

Brno, Czech Republic, 63400

Olonouc, Czech Republic, 77520

Praha 10, Czech Republic, 10034

Praha 4, Czech Republic, 14000

Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

Paris, Cedex 12, France, 75557

France, Cedex 1

Nantes, Cedex 1, France, 44093

France

Besancon, France, 25030

Bordeaux, France, 33000

Dijon, France, 21079

Lyon, France, 69003

Lyon, France, 69006

Marseille, France, 13008

Paris, France, 75010

Paris, France, 75015

Germany, Baden-Württemberg

Freiburg, Baden-Württemberg, Germany, 79106

Heidelberg, Baden-Württemberg, Germany, 69120

Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

München, Bayern, Germany, 81675

Regensburg, Bayern, Germany, 93053

Germany, Hessen

Darmstadt, Hessen, Germany, 64297

Germany, Nordrhein-Westfalen

Aachen, Nordrhein-Westfalen, Germany, 52074

Bonn, Nordrhein-Westfalen, Germany, 53105

Essen, Nordrhein-Westfalen, Germany, 45122

Köln, Nordrhein-Westfalen, Germany, 50924

Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

Ludwigshafen, Rheinland-Pfalz, Germany, 67063

Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

Homburg, Saarland, Germany, 66424

Germany, Sachsen

Dresden, Sachsen, Germany, 01307

Dresden, Sachsen, Germany, 06067

Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

Kiel, Schleswig-Holstein, Germany, 24105

Lübeck, Schleswig-Holstein, Germany, 23538

Germany

Berlin, Germany, 12200

Hamburg, Germany, 20251

Hungary

Budapest, Hungary, 1083

Budapest, Hungary, 1106

Budapest, Hungary, 1133

Veszprem, Hungary, 8200

India, Gujrat

Ahemedabad - 4, Gujrat, India, 380009

India, Maharashtra

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil N?du

Chennai, Tamil N?du, India, 600 006

Coimbatore, Tamil N?du, India, 641014

Madurai, Tamil N?du, India, 625 020

Pondicherry, Tamil N?du, India, 600007

India

Bangalore, India, 560010

Chandigarh, India, 160012

Hyderabad, India, 500 034

Kerala, India, 683572

Kolkata, India, 700073

Mumbai, India, 400 050

New Delhi, India, 110002

New Delhi, India, 110029

Orissa, India, 751 024

Israel

Afula, Israel

Beer Sheva, Israel

Haifa, Israel, 34362

Jerusalem, Israel, 91120

Kfar Saba, Israel

Petach Tikva, Israel, 49100

Rehovot, Israel, 76100

Tel Aviv, Israel, 64239

Tel Hashomer, Israel

Zrifin, Israel, 70300

Italy

Ancona, Italy, 60126

Bari, Italy, 70124

Catania, Italy, 95123

Genova, Italy, 16132

Milano, Italy, 20122

Milano, Italy, 20132

Milano, Italy, 20157

Padova, Italy, 35128

Roma, Italy, 00133

Roma, Italy, 00168

Roma, Italy, 00198

Torino, Italy, 10122

Udine, Italy, 33100

Varese, Italy, 21100

Verona, Italy, 37121

Japan, Aichi

Nagoya, Aichi, Japan, 466-8560

Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

Kita, Kagawa, Japan, 761-0793

Japan, Osaka

Hirakata, Osaka, Japan, 573-1191

Suita, Osaka, Japan, 565-0871

Japan, Shiga

Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

Chiyoda-ku, Tokyo, Japan, 101-8309

Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

Fukuoka, Japan, 812-8582

Fukushima, Japan, 960-1295

Kagoshima, Japan, 890-8520

Kyoto, Japan, 606-8507

Korea, Republic of, Gyeonggido

Seongnam, Gyeonggido, Korea, Republic of, 463 707

Korea, Republic of

Incheon, Korea, Republic of, 405-760

Seoul, Korea, Republic of, 110 744

Seoul, Korea, Republic of, 137 701

Seoul, Korea, Republic of, 138-736

Seoul, Korea, Republic of, 152-703

Latvia

Riga, Latvia, 1002

Riga, Latvia, 1009

Riga, Latvia, 1050

Mexico, Distrito Federal

Mexico City, Distrito Federal, Mexico, 06800

Mexico, Jalisco

Zapopan, Jalisco, Mexico, 45060

Mexico, México

Metepec, México, Mexico, 52140

Mexico, Nuevo Leon

Monterrey, Nuevo Leon, Mexico, 64060

Monterrey, Nuevo Leon, Mexico, 64480

Mexico

Chihuahua, Mexico, 31238

Mexico City, Mexico, 06030

México D.F., Mexico, 04030

Netherlands, ZA

Leiden, ZA, Netherlands, 2333

Netherlands

Amsterdam, Netherlands, 1100 DD

Groningen, Netherlands, 9713 GZ

Nijmegen, Netherlands, 6525 EX

Rotterdam, Netherlands, 3000 CA

Poland

Bydgoszcz, Poland, 85-631

Gdansk, Poland, 80-952

Katowice, Poland, 40-760

Poznan, Poland, 61-848

Warszaa, Poland, 02-005

Warszawa, Poland, 00-416

Wroclaw, Poland, 50-368

Portugal

Coimbra, Portugal, 3000-548

Porto, Portugal, 4200-319

Singapore

Singapore, Singapore, 119074

Singapore, Singapore, 159964

Singapore, Singapore, 168751

Singapore, Singapore, 308433

Slovakia

Banska Bystrica, Slovakia, 97517

Bratislava, Slovakia, 81369

Spain, A Coruña

Santiago de Compostela, A Coruña, Spain, 15705

Spain, Asturias

Oviedo, Asturias, Spain, 33012

Spain, Navarra

Pamplona, Navarra, Spain, 31008

Spain

Alicante, Spain, 03016

Barcelona, Spain, 08017

Barcelona, Spain, 08022

Barcelona, Spain, 08035

Barcelona, Spain, 08036

Madrid, Spain, 28002

Madrid, Spain, 28046

Malaga, Spain, 29010

Sevilla, Spain, 41009

Sevilla, Spain, 41013

Valencia, Spain, 46014

Valencia, Spain, 46015

Valladolid, Spain, 47005

Sweden

Linköping, Sweden, 58185

Stockholm, Sweden, 11282

Örebro, Sweden, 70185

Switzerland

Basel, Switzerland, 4031

Bern, Switzerland, 3010

Genève, Switzerland, 1211

Zürich, Switzerland, 8091

United Kingdom, Hampshire

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Surrey

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

Aberdeen, United Kingdom, AB25 2ZN

Belfast, United Kingdom, BT12 6BA

Birmingham, United Kingdom, B4 7ET

Liverpool, United Kingdom, L7 8XP

London, United Kingdom, NW1 5QH

London, United Kingdom, SE5 9RS

Plymouth, United Kingdom, PL4 6PL

Torquay, United Kingdom, TQ2 7AA

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	◉	◉	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: October 6, 2010 (v21)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD)

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification: October 2010

Overall Status: Active, not recruiting

Study Start: April 2008

Primary Completion: September 2010 [Anticipated]

Study Completion: August 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: October 6, 2010

Last Update Posted: October 7, 2010 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1211 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye (BAY86-5321) 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

Buenos Aires, Capital Federal, Argentina, C1015ABO

Buenos Aires, Capital Federal, Argentina, C1023AAQ

Buenos Aires, Capital Federal, Argentina, C1122AAI

Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

Córdoba, Argentina, X5000IIT

Australia, New South Wales

Chatswood, New South Wales, Australia, 2067

Sydney, New South Wales, Australia, 2000

Westmead, New South Wales, Australia, 2145

Australia, Victoria

East Melbourne, Victoria, Australia, 3002

Parkville, Victoria, Australia, 3050

Australia, Western Australia

Nedlands, Western Australia, Australia, 6009

Australia

Parramatta, Australia, 2150

Austria

Innsbruck, Austria, 6020

Linz, Austria, 4021

Wien, Austria, 1090

Belgium

Liege, Belgium, 4000

Brazil, Sao Paulo

São Paulo, Sao Paulo, Brazil, 05651-901

Brazil, SP

Araraquara, SP, Brazil, 14801-310

Sao Paulo, SP, Brazil, 04023-062

Brazil

Minas Gerais, Brazil, 30150-270

Colombia, Antioquia

Medellín, Antioquia, Colombia

Colombia

Bogota, Colombia

Cali, Colombia

Medellín, Colombia

Czech Republic

Brno, Czech Republic, 62500

Olomouc, Czech Republic, 775 20

Praha 10, Czech Republic, 10034

Praha 4, Czech Republic, 14000

Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

Paris, Cedex 12, France, 75557

France, Cedex 1

Nantes, Cedex 1, France, 44093

France

Besancon, France, 25030

Bordeaux, France, 33000

Dijon, France, 21079

Lyon, France, 69003

Lyon, France, 69006

Marseille, France, 13008

Paris, France, 75010

Paris, France, 75015

Germany, Baden-Württemberg

Freiburg, Baden-Württemberg, Germany, 79106

Heidelberg, Baden-Württemberg, Germany, 69120

Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

München, Bayern, Germany, 81675

Regensburg, Bayern, Germany, 93053

Germany, Hessen

Darmstadt, Hessen, Germany, 64297

Germany, Nordrhein-Westfalen

Aachen, Nordrhein-Westfalen, Germany, 52074

Bonn, Nordrhein-Westfalen, Germany, 53105

Essen, Nordrhein-Westfalen, Germany, 45122

Köln, Nordrhein-Westfalen, Germany, 50924

Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

Ludwigshafen, Rheinland-Pfalz, Germany, 67063

Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

Homburg, Saarland, Germany, 66424

Germany, Sachsen

Dresden, Sachsen, Germany, 01067

Dresden, Sachsen, Germany, 01307

Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

Kiel, Schleswig-Holstein, Germany, 24105

Lübeck, Schleswig-Holstein, Germany, 23538

Germany

Berlin, Germany, 12200

Hamburg, Germany, 20251

Hungary

Budapest, Hungary, 1036

Budapest, Hungary, 1083

Budapest, Hungary, 1106

Veszprem, Hungary, 8200

India, Gujrat

Ahemedabad - 4, Gujrat, India, 380009

India, Maharashtra

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

Chennai, Tamil Nadu, India, 600 006

Coimbatore, Tamil Nadu, India, 641014

Madurai, Tamil Nadu, India, 625 020

Pondicherry, Tamil Nadu, India, 600007

India

Bangalore, India, 560010

Chandigarh, India, 160012

Hyderabad, India, 500 034

Kerala, India, 683572

Kolkata, India, 700073

Mumbai, India, 400 050

New Delhi, India, 110002

New Delhi, India, 110029

Orissa, India, 751 024

Israel

Afula, Israel

Beer Sheva, Israel

Haifa, Israel, 34362

Jerusalem, Israel, 91120

Kfar Saba, Israel

Petach Tikva, Israel, 49100

Rehovot, Israel, 76100

Tel Aviv, Israel, 64239

Tel Hashomer, Israel

Zrifin, Israel, 70300

Italy

Ancona, Italy, 60126

Bari, Italy, 70124

Catania, Italy, 95123

Genova, Italy, 16132

Milano, Italy, 20122

Milano, Italy, 20132

Milano, Italy, 20157

Padova, Italy, 35128

Roma, Italy, 00133

Roma, Italy, 00168

Roma, Italy, 00198

Torino, Italy, 10122

Udine, Italy, 33100

Varese, Italy, 21100

Verona, Italy, 37121

Japan, Aichi

Nagoya, Aichi, Japan, 466-8560

Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

Kita, Kagawa, Japan, 761-0793

Japan, Osaka

Hirakata, Osaka, Japan, 573-1191

Suita, Osaka, Japan, 565-0871

Japan, Shiga

Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

Chiyoda-ku, Tokyo, Japan, 101-8309

Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

Fukuoka, Japan, 812-8582

Fukushima, Japan, 960-1295

Kagoshima, Japan, 890-8520

Kyoto, Japan, 606-8507

Korea, Republic of, Kyunggi

Seongnam, Kyunggi, Korea, Republic of, 463 707

Korea, Republic of

Incheon, Korea, Republic of, 405-760

Seoul, Korea, Republic of, 110 744

Seoul, Korea, Republic of, 137 701

Seoul, Korea, Republic of, 138-736

Seoul, Korea, Republic of, 152-703

Latvia

Riga, Latvia, 1002

Riga, Latvia, 1009

Riga, Latvia

Mexico, DF

Mexico City, DF, Mexico, 06800

Mexico, Edo. De Mexico

Metepec, Edo. De Mexico, Mexico, 52140

Mexico, Jalisco

Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

Monterrey, Nuevo Leon, Mexico, 64060

Monterrey, Nuevo Leon, Mexico, 64460

Mexico

Chihuahua, Mexico, 31238

Mexico City, Mexico, 06030

México D.F., Mexico, 04030

Netherlands, ZA

Leiden, ZA, Netherlands, 2333

Netherlands

Amsterdam, Netherlands, 1100 DD

Groningen, Netherlands, 9713 GZ

Nijmegen, Netherlands, 6525 EX

Rotterdam, Netherlands, 3000 CA

Poland

Bydgoszcz, Poland, 85-631

Gdansk, Poland, 80-952

Katowice, Poland, 40-760

Poznan, Poland, 61-848

Warszawa, Poland, 00-416

Warszawa, Poland, 02-005

Wroclaw, Poland, 50-368

Portugal

Coimbra, Portugal, 3000-548

Porto, Portugal, 4200-319

Singapore

Singapore, Singapore, 119074

Singapore, Singapore, 159964

Singapore, Singapore, 168751

Singapore, Singapore, 308433

Slovakia

Banska Bystrica, Slovakia, 97517

Bratislava, Slovakia, 81369

Spain, Asturias

Oviedo, Asturias, Spain, 33012

Spain, La Coruna

Santiago de Compostela, La Coruna, Spain, 15705

Spain, Navarra

Pamplona, Navarra, Spain, 31008

Spain

Alicante, Spain, 03016

Barcelona, Spain, 08017

Barcelona, Spain, 08022

Barcelona, Spain, 08035

Barcelona, Spain, 08036

Madrid, Spain, 28002

Madrid, Spain, 28046

Malaga, Spain, 29010

Sevilla, Spain, 41009

Sevilla, Spain, 41013

Valencia, Spain, 46014

Valencia, Spain, 46015

Valladolid, Spain, 47005

Sweden

Linköping, Sweden, 58185

Stockholm, Sweden, 11282

Örebro, Sweden, 70185

Switzerland

Basel, Switzerland, 4031

Bern, Switzerland, 3010

Genève, Switzerland, 1211

Zürich, Switzerland, 8091

United Kingdom, Hampshire

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Surrey

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

Aberdeen, United Kingdom, AB25 2ZN

Belfast, United Kingdom, BT12 6BA

Birmingham, United Kingdom, B4 7ET

Liverpool, United Kingdom, L7 8XP

London, United Kingdom, NW1 5QH

London, United Kingdom, SE5 9RS

Plymouth, United Kingdom, PL4 6PL

Torquay, United Kingdom, TQ2 7AA

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	◉	◉	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: July 9, 2010 (v20)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD)

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification: July 2010

Overall Status: Active, not recruiting

Study Start: April 2008

Primary Completion: September 2010 [Anticipated]

Study Completion: August 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: July 9, 2010

Last Update Posted: July 12, 2010 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1211 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Regeneron Ex. 2001
Fresenius v. Regeneron
IPR2025-01269
Page 2150 of 3000

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye (BAY86-5321) 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

Buenos Aires, Capital Federal, Argentina, C1015ABO

Buenos Aires, Capital Federal, Argentina, C1023AAQ

Buenos Aires, Capital Federal, Argentina, C1122AAI

Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

Córdoba, Argentina, X5000IIT

Australia, New South Wales

Chatswood, New South Wales, Australia, 2067

Sydney, New South Wales, Australia, 2000

Westmead, New South Wales, Australia, 2145

Australia, Victoria

East Melbourne, Victoria, Australia, 3002

Parkville, Victoria, Australia, 3050

Australia, Western Australia

Nedlands, Western Australia, Australia, 6009

Australia

Parramatta, Australia, 2150

Austria

Innsbruck, Austria, 6020

Linz, Austria, 4021

Wien, Austria, 1090

Belgium

Liege, Belgium, 4000

Brazil, Sao Paulo

São Paulo, Sao Paulo, Brazil, 05651-901

Brazil, SP

Araraquara, SP, Brazil, 14801-310

Sao Paulo, SP, Brazil, 04023-062

Brazil

Minas Gerais, Brazil, 30150-270

Colombia, Antioquia

Medellín, Antioquia, Colombia

Colombia

Bogota, Colombia

Cali, Colombia

Medellín, Colombia

Czech Republic

Brno, Czech Republic, 62500

Olomouc, Czech Republic, 775 20

Praha 10, Czech Republic, 10034

Praha 4, Czech Republic, 14000

Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

Paris, Cedex 12, France, 75557

France, Cedex 1

Nantes, Cedex 1, France, 44093

France

Besancon, France, 25030

Bordeaux, France, 33000

Dijon, France, 21079

Lyon, France, 69003

Lyon, France, 69006

Marseille, France, 13008

Paris, France, 75010

Paris, France, 75015

Germany, Baden-Württemberg

Freiburg, Baden-Württemberg, Germany, 79106

Heidelberg, Baden-Württemberg, Germany, 69120

Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

München, Bayern, Germany, 81675

Regensburg, Bayern, Germany, 93053

Germany, Hessen

Darmstadt, Hessen, Germany, 64297

Germany, Nordrhein-Westfalen

Aachen, Nordrhein-Westfalen, Germany, 52074

Bonn, Nordrhein-Westfalen, Germany, 53105

Essen, Nordrhein-Westfalen, Germany, 45122

Köln, Nordrhein-Westfalen, Germany, 50924

Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

Ludwigshafen, Rheinland-Pfalz, Germany, 67063

Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

Homburg, Saarland, Germany, 66424

Germany, Sachsen

Dresden, Sachsen, Germany, 01067

Dresden, Sachsen, Germany, 01307

Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

Kiel, Schleswig-Holstein, Germany, 24105

Lübeck, Schleswig-Holstein, Germany, 23538

Germany

Berlin, Germany, 12200

Hamburg, Germany, 20251

Hungary

Budapest, Hungary, 1036

Budapest, Hungary, 1083

Budapest, Hungary, 1106

Veszprem, Hungary, 8200

India, Gujrat

Ahemedabad - 4, Gujrat, India, 380009

India, Maharashtra

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

Chennai, Tamil Nadu, India, 600 006

Coimbatore, Tamil Nadu, India, 641014

Madurai, Tamil Nadu, India, 625 020

Pondicherry, Tamil Nadu, India, 600007

India

Bangalore, India, 560010

Chandigarh, India, 160012

Hyderabad, India, 500 034

Kerala, India, 683572

Kolkata, India, 700073

Mumbai, India, 400 050

New Delhi, India, 110002

New Delhi, India, 110029

Orissa, India, 751 024

Israel

Afula, Israel

Beer Sheva, Israel

Haifa, Israel, 34362

Jerusalem, Israel, 91120

Kfar Saba, Israel

Petach Tikva, Israel, 49100

Rehovot, Israel, 76100

Tel Aviv, Israel, 64239

Tel Hashomer, Israel

Zrifin, Israel, 70300

Italy

Ancona, Italy, 60126

Bari, Italy, 70124

Catania, Italy, 95123

Genova, Italy, 16132

Milano, Italy, 20122

Milano, Italy, 20132

Milano, Italy, 20157

Padova, Italy, 35128

Roma, Italy, 00133

Roma, Italy, 00168

Roma, Italy, 00198

Torino, Italy, 10122

Udine, Italy, 33100

Varese, Italy, 21100

Verona, Italy, 37121

Japan, Aichi

Nagoya, Aichi, Japan, 466-8560

Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

Kita, Kagawa, Japan, 761-0793

Japan, Osaka

Hirakata, Osaka, Japan, 573-1191

Suita, Osaka, Japan, 565-0871

Japan, Shiga

Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

Chiyoda-ku, Tokyo, Japan, 101-8309

Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

Fukuoka, Japan, 812-8582

Fukushima, Japan, 960-1295

Kagoshima, Japan, 890-8520

Kyoto, Japan, 606-8507

Korea, Republic of, Kyunggi

Seongnam, Kyunggi, Korea, Republic of, 463 707

Korea, Republic of

Incheon, Korea, Republic of, 405-760

Seoul, Korea, Republic of, 110 744

Seoul, Korea, Republic of, 137 701

Seoul, Korea, Republic of, 138-736

Seoul, Korea, Republic of, 152-703

Latvia

Riga, Latvia, 1002

Riga, Latvia, 1009

Riga, Latvia

Mexico, DF

Mexico City, DF, Mexico, 06800

Mexico, Edo. De Mexico

Metepec, Edo. De Mexico, Mexico, 52140

Mexico, Jalisco

Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

Monterrey, Nuevo Leon, Mexico, 64060

Monterrey, Nuevo Leon, Mexico, 64460

Mexico

Chihuahua, Mexico, 31238

Mexico City, Mexico, 06030

México D.F., Mexico, 04030

Netherlands, ZA

Leiden, ZA, Netherlands, 2333

Netherlands

Amsterdam, Netherlands, 1100 DD

Groningen, Netherlands, 9713 GZ

Nijmegen, Netherlands, 6525 EX

Rotterdam, Netherlands, 3000 CA

Poland

Bydgoszcz, Poland, 85-631

Gdansk, Poland, 80-952

Katowice, Poland, 40-760

Poznan, Poland, 61-848

Warszawa, Poland, 00-416

Warszawa, Poland, 02-005

Wroclaw, Poland, 50-368

Portugal

Coimbra, Portugal, 3000-548

Porto, Portugal, 4200-319

Singapore

Singapore, Singapore, 119074

Singapore, Singapore, 159964

Singapore, Singapore, 168751

Singapore, Singapore, 308433

Slovakia

Banska Bystrica, Slovakia, 97517

Bratislava, Slovakia, 81369

Spain, Asturias

Oviedo, Asturias, Spain, 33012

Spain, La Coruna

Santiago de Compostela, La Coruna, Spain, 15705

Spain, Navarra

Pamplona, Navarra, Spain, 31008

Spain

Alicante, Spain, 03016

Barcelona, Spain, 08017

Barcelona, Spain, 08022

Barcelona, Spain, 08035

Barcelona, Spain, 08036

Madrid, Spain, 28002

Madrid, Spain, 28046

Malaga, Spain, 29010

Sevilla, Spain, 41009

Sevilla, Spain, 41013

Valencia, Spain, 46014

Valencia, Spain, 46015

Valladolid, Spain, 47005

Sweden

Linköping, Sweden, 58185

Stockholm, Sweden, 11282

Örebro, Sweden, 70185

Switzerland

Basel, Switzerland, 4031

Bern, Switzerland, 3010

Genève, Switzerland, 1211

Zürich, Switzerland, 8091

United Kingdom, Hampshire

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Surrey

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

Aberdeen, United Kingdom, AB25 2ZN

Belfast, United Kingdom, BT12 6BA

Birmingham, United Kingdom, B4 7ET

Liverpool, United Kingdom, L7 8XP

London, United Kingdom, NW1 5QH

London, United Kingdom, SE5 9RS

Plymouth, United Kingdom, PL4 6PL

Torquay, United Kingdom, TQ2 7AA

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	◉	◉	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: February 19, 2010 (v19)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

	Related Macular Degeneration (AMD) (VIEW 2)
Official Title:	A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD)
Secondary IDs:	EurdaCT No.: 2007-000583-25

Study Status

Record Verification:	February 2010
Overall Status:	Active, not recruiting
Study Start:	April 2008
Primary Completion:	October 2010 [Anticipated]
Study Completion:	September 2011 [Anticipated]
First Submitted:	March 12, 2008
First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	February 19, 2010
Last Update Posted:	February 22, 2010 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1211 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Regeneron Ex. 2001
Fresenius v. Regeneron
IPR2025-01269
Page 2169 of 3000

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye (BAY86-5321) 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye (BAY86-5321) 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

Buenos Aires, Capital Federal, Argentina, C1015ABO

Buenos Aires, Capital Federal, Argentina, C1023AAQ

Buenos Aires, Capital Federal, Argentina, C1122AAI

Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

Córdoba, Argentina, X5000IIT

Australia, New South Wales

Chatswood, New South Wales, Australia, 2067

Sydney, New South Wales, Australia, 2000

Westmead, New South Wales, Australia, 2145

Australia, Victoria

East Melbourne, Victoria, Australia, 3002

Parkville, Victoria, Australia, 3050

Australia, Western Australia

Nedlands, Western Australia, Australia, 6009

Australia

Parramatta, Australia, 2150

Austria, Tirol

Innsbruck, Tirol, Austria, 6020

Austria

Linz, Austria, 4021

Wien, Austria, 1090

Belgium

Liege, Belgium, 4000

Brazil, SP

Araraquara, SP, Brazil, 14801-310

Sao Paulo, SP, Brazil, 04023-900

São Paulo, SP, Brazil, 05651-901

Brazil

Minas Gerais, Brazil, 30150-270

Colombia

Bogota, Colombia

Cali, Colombia

Medellín, Colombia

Czech Republic

Brno, Czech Republic, 62500

Olomouc, Czech Republic, 775 20

Praha 10, Czech Republic, 10034

Praha 4, Czech Republic, 14000

Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

Paris, Cedex 12, France, 75557

France

Besancon, France, 25030

Bordeaux, France, 33000

Dijon Cedex, France, BP 1542-21

Lyon, France, 69003

Lyon, France, 69006

Marseille, France, 13008

Nantes Cedex, France, 44035

Paris Cedex 10, France, 75475

Paris, France, 75015

Germany, Baden-Württemberg

Freiburg, Baden-Württemberg, Germany, 79106

Heidelberg, Baden-Württemberg, Germany, 69120

Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

München, Bayern, Germany, 81675

Regensburg, Bayern, Germany, 93053

Germany, Hessen

Darmstadt, Hessen, Germany, 64276

Germany, Nordrhein-Westfalen

Aachen, Nordrhein-Westfalen, Germany, 52074

Bonn, Nordrhein-Westfalen, Germany, 53105

Essen, Nordrhein-Westfalen, Germany, 45147

Köln, Nordrhein-Westfalen, Germany, 50931

Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

Ludwigshafen, Rheinland-Pfalz, Germany, 67063

Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

Homburg, Saarland, Germany, 66421

Germany, Sachsen

Dresden, Sachsen, Germany, 01067

Dresden, Sachsen, Germany, 01307

Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

Kiel, Schleswig-Holstein, Germany, 24105

Lübeck, Schleswig-Holstein, Germany, 23538

Germany

Berlin, Germany, 12200

Hamburg, Germany, 20251

Hungary

Budapest, Hungary, 1036

Budapest, Hungary, 1089

Budapest, Hungary, 1106

Veszprem, Hungary, 8200

India, Maharashtra

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

Chennai, Tamil Nadu, India, 600 006

Coimbatore, Tamil Nadu, India, 641014

Madurai, Tamil Nadu, India, 625 020

Pondicherry, Tamil Nadu, India, 600007

India

Bangalore, India, 560010

Chandigarh, India, 160062

Gugarat, India

Hyderabad, India, 500 034

Kerala, India, 683572

Kolkata, India, 700073

Mumbai, India, 400 050

New Delhi, India, 110002

New Delhi, India, 110029

Orissa, India, 751 024

Israel

Afula, Israel, 18101

Beer Sheva, Israel, 84101

Haifa, Israel, 34362

Jerusalem, Israel, 91120

Kfar Saba, Israel, 44281

Petach Tikva, Israel, 49100

Rehovot, Israel, 76100

Tel Aviv, Israel, 64239

Tel Hashomer, Israel, 52621

Zerifin, Israel, 70300

Italy

Ancona, Italy, 60020

Bari, Italy, 70124

Catania, Italy, 95123

Genova, Italy, 16132

Milano, Italy, 20132

Milano, Italy, 20142

Padova, Italy, 35128

Roma, Italy, 00133

Roma, Italy, 00168

Roma, Italy, 00185

Torino, Italy, 10126

Udine, Italy, 33100

Varese, Italy, 21100

Verona, Italy, 37121

Japan, Aichi

Nagoya, Aichi, Japan, 466-8560

Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

Kita, Kagawa, Japan, 761-0793

Japan, Osaka

Hirakata, Osaka, Japan, 573-1191

Suita, Osaka, Japan, 565-0871

Japan, Shiga

Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

Chiyoda-ku, Tokyo, Japan, 101-8309

Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

Fukuoka, Japan, 812-8582

Fukushima, Japan, 960-1295

Kagoshima, Japan, 890-8520

Kyoto, Japan, 606-8507

Korea, Republic of, Gyeonggi-do

Seongnam, Gyeonggi-do, Korea, Republic of, 463 707

Korea, Republic of, Korea

Seoul, Korea, Korea, Republic of, 110-744

Korea, Republic of

Incheon, Korea, Republic of, 405-760

Seoul, Korea, Republic of, 110 744

Seoul, Korea, Republic of, 138-736

Seoul, Korea, Republic of, 152-703

Latvia

Riga, Latvia, 1002

Riga, Latvia, 1009

Riga, Latvia

Mexico, DF

Mexico City, DF, Mexico, 06800

Mexico, Estado de México

Metepec, Estado de México, Mexico, 52140

Mexico, Jalisco

Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

Monterrey, Nuevo Leon, Mexico, 64060

Monterrey, Nuevo Leon, Mexico, 64460

Mexico

Chihuahua, Mexico, 31238

Mexico City, Mexico, 06030

México D.F., Mexico, 04030

Netherlands, DD

Amsterdam, DD, Netherlands, 1100

Netherlands, EX

Nijmegen, EX, Netherlands, 6525

Netherlands

Groningen, Netherlands, 9713 GZ

Leiden, Netherlands, 2333 ZA

Rotterdam, Netherlands, 3015 GD

Poland

Bydgoszcz, Poland, 85-631

Gdansk, Poland, 80-952

Katowice, Poland, 40-760

Poznan, Poland, 60-355

Warszawa, Poland, 00-416

Warszawa, Poland, 02-005

Wroclaw, Poland, 50-368

Portugal

Coimbra, Portugal, 3000-548

Porto, Portugal, 4200-319

Singapore

Singapore, Singapore, 119074

Singapore, Singapore, 159964

Singapore, Singapore, 308433

Slovakia

Banska Bystrica, Slovakia, 97517

Bratislava, Slovakia, 813 69

Spain, Asturias

Oviedo, Asturias, Spain, 33012

Spain, La Coruna

Santiago de Compostela, La Coruna, Spain, 15705

Spain

Alicante, Spain, 03016

Barcelona, Spain, 08017

Barcelona, Spain, 08022

Barcelona, Spain, 08035

Barcelona, Spain, 08036

Madrid, Spain, 28002

Madrid, Spain, 28046

Malaga, Spain, 29010

Pamplona, Spain, 31008

Sevilla, Spain, 41013

Sevilla, Spain, 41071

Valencia, Spain, 46014

Valencia, Spain, 46015

Valladolid, Spain, 47005

Sweden

Linköping, Sweden, 58185

Stockholm, Sweden, 11282

Örebro, Sweden, 70185

Switzerland

Basel, Switzerland, 4031

Bern, Switzerland, 3010

Genève, Switzerland, 1211

Zürich, Switzerland, 8091

United Kingdom, Devon

Torbay, Devon, United Kingdom, TQ2 7AA

United Kingdom, Grampian

Aberdeen, Grampian, United Kingdom, AB25 2ZN

United Kingdom, Greater London

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Merseyside

Liverpool, Merseyside, United Kingdom, L7 8XP

United Kingdom, Northern Ireland

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Surrey

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

Birmingham, United Kingdom, B4 7ET

London, United Kingdom, NW1 5QH

Plymouth, United Kingdom, PL6 8BX

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	◉	◉	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: November 19, 2009 (v18)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification: November 2009

Overall Status: Active, not recruiting

Study Start: April 2008

Primary Completion: July 2011 [Anticipated]

Study Completion: September 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: November 19, 2009

Last Update Posted: November 20, 2009 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

Buenos Aires, Capital Federal, Argentina, C1015ABO

Buenos Aires, Capital Federal, Argentina, C1023AAQ

Buenos Aires, Capital Federal, Argentina, C1122AAI

Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

Córdoba, Argentina, X5000IIT

Australia, New South Wales

Chatswood, New South Wales, Australia, 2067

Sydney, New South Wales, Australia, 2000

Westmead, New South Wales, Australia, 2145

Australia, Victoria

East Melbourne, Victoria, Australia, 3002

Parkville, Victoria, Australia, 3050

Australia, Western Australia

Nedlands, Western Australia, Australia, 6009

Australia

Parramatta, Australia, 2150

Austria, Tirol

Innsbruck, Tirol, Austria, 6020

Austria

Linz, Austria, 4021

Wien, Austria, 1090

Belgium

Liege, Belgium, 4000

Brazil, SP

Araraquara, SP, Brazil, 14801-310

Sao Paulo, SP, Brazil, 04023-900

São Paulo, SP, Brazil, 05651-901

Brazil

Minas Gerais, Brazil, 30150-270

Colombia

Bogota, Colombia

Cali, Colombia

Medellín, Colombia

Czech Republic

Brno, Czech Republic, 62500

Olomouc, Czech Republic, 775 20

Praha 10, Czech Republic, 10034

Praha 4, Czech Republic, 14000

Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

Paris, Cedex 12, France, 75557

France

Besancon, France, 25030

Bordeaux, France, 33000

Dijon Cedex, France, BP 1542-21

Lyon, France, 69003

Lyon, France, 69006

Marseille, France, 13008

Nantes Cedex, France, 44035

Paris Cedex 10, France, 75475

Paris, France, 75015

Germany, Baden-Württemberg

Freiburg, Baden-Württemberg, Germany, 79106

Heidelberg, Baden-Württemberg, Germany, 69120

Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

München, Bayern, Germany, 81675

Regensburg, Bayern, Germany, 93053

Germany, Hessen

Darmstadt, Hessen, Germany, 64276

Germany, Nordrhein-Westfalen

Aachen, Nordrhein-Westfalen, Germany, 52074

Bonn, Nordrhein-Westfalen, Germany, 53105

Essen, Nordrhein-Westfalen, Germany, 45147

Köln, Nordrhein-Westfalen, Germany, 50931

Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

Ludwigshafen, Rheinland-Pfalz, Germany, 67063

Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

Homburg, Saarland, Germany, 66421

Germany, Sachsen

Dresden, Sachsen, Germany, 01067

Dresden, Sachsen, Germany, 01307

Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

Kiel, Schleswig-Holstein, Germany, 24105

Lübeck, Schleswig-Holstein, Germany, 23538

Germany

Berlin, Germany, 12200

Hamburg, Germany, 20251

Hungary

Budapest, Hungary, 1036

Budapest, Hungary, 1089

Budapest, Hungary, 1106

Veszprem, Hungary, 8200

India, Maharashtra

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

Chennai, Tamil Nadu, India, 600 006

Coimbatore, Tamil Nadu, India, 641014

Madurai, Tamil Nadu, India, 625 020

Pondicherry, Tamil Nadu, India, 600007

India

Bangalore, India, 560010

Chandigarh, India, 160062

Gugarat, India

Hyderabad, India, 500 034

Kerala, India, 683572

Kolkata, India, 700073

Mumbai, India, 400 050

New Delhi, India, 110002

New Delhi, India, 110029

Orissa, India, 751 024

Israel

Afula, Israel, 18101

Beer Sheva, Israel, 84101

Haifa, Israel, 34362

Jerusalem, Israel, 91120

Kfar Saba, Israel, 44281

Petach Tikva, Israel, 49100

Rehovot, Israel, 76100

Tel Aviv, Israel, 64239

Tel Hashomer, Israel, 52621

Zerifin, Israel, 70300

Italy

Ancona, Italy, 60020

Bari, Italy, 70124

Catania, Italy, 95123

Genova, Italy, 16132

Milano, Italy, 20132

Milano, Italy, 20142

Padova, Italy, 35128

Roma, Italy, 00133

Roma, Italy, 00168

Roma, Italy, 00185

Torino, Italy, 10126

Udine, Italy, 33100

Varese, Italy, 21100

Japan, Aichi

Nagoya, Aichi, Japan, 466-8560

Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

Kita, Kagawa, Japan, 761-0793

Japan, Osaka

Hirakata, Osaka, Japan, 573-1191

Suita, Osaka, Japan, 565-0871

Japan, Shiga

Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

Chiyoda-ku, Tokyo, Japan, 101-8309

Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

Fukuoka, Japan, 812-8582

Fukushima, Japan, 960-1295

Kagoshima, Japan, 890-8520

Kyoto, Japan, 606-8507

Korea, Republic of, Gyeonggi-do

Seongnam, Gyeonggi-do, Korea, Republic of, 463 707

Korea, Republic of, Korea

Seoul, Korea, Korea, Republic of, 110-744

Korea, Republic of

Incheon, Korea, Republic of, 405-760

Seoul, Korea, Republic of, 110 744

Seoul, Korea, Republic of, 138-736

Seoul, Korea, Republic of, 152-703

Latvia

Riga, Latvia, 1002

Riga, Latvia, 1009

Mexico, DF

Mexico City, DF, Mexico, 06800

Mexico, Jalisco

Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

Monterrey, Nuevo Leon, Mexico, 64060

Monterrey, Nuevo Leon, Mexico, 64460

Mexico

Chihuahua, Mexico, 31238

Mexico City, Mexico, 06030

México D.F., Mexico, 04030

Netherlands, EX

Nijmegen, EX, Netherlands, 6525

Netherlands

Groningen, Netherlands, 9713 GZ

Leiden, Netherlands, 2333 ZA

Rotterdam, Netherlands, 3015 GD

Poland

Bydgoszcz, Poland, 85-631

Gdansk, Poland, 80-952

Katowice, Poland, 40-760

Poznan, Poland, 60-355

Warszawa, Poland, 00-416

Warszawa, Poland, 02-005

Wroclaw, Poland, 50-368

Portugal

Coimbra, Portugal, 3000-548

Porto, Portugal, 4200-319

Singapore

Ask Contact, Singapore, 168751

Singapore, Singapore, 119074

Singapore, Singapore, 159964

Singapore, Singapore, 308433

Slovakia

Banska Bystrica, Slovakia, 97517

Bratislava, Slovakia, 813 69

Spain, Asturias

Oviedo, Asturias, Spain, 33012

Spain, La Coruna

Santiago de Compostela, La Coruna, Spain, 15705

Spain

Alicante, Spain, 03016

Barcelona, Spain, 08017

Barcelona, Spain, 08022

Barcelona, Spain, 08035

Barcelona, Spain, 08036

Madrid, Spain, 28002

Madrid, Spain, 28046

Malaga, Spain, 29010

Pamplona, Spain, 31008

Sevilla, Spain, 41013

Sevilla, Spain, 41071

Valencia, Spain, 46014

Valencia, Spain, 46015

Valladolid, Spain, 47005

Sweden

Linköping, Sweden, 58185

Stockholm, Sweden, 11282

Örebro, Sweden, 70185

Switzerland

Basel, Switzerland, 4031

Bern, Switzerland, 3010

Genève, Switzerland, 1211

Zürich, Switzerland, 8091

United Kingdom, Devon

Torbay, Devon, United Kingdom, TQ2 7AA

United Kingdom, Grampian

Aberdeen, Grampian, United Kingdom, AB25 2ZN

United Kingdom, Greater London

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Merseyside

Liverpool, Merseyside, United Kingdom, L7 8XP

United Kingdom, Northern Ireland

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Surrey

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

Birmingham, United Kingdom, B4 7ET

London, United Kingdom, NW1 5QH

Plymouth, United Kingdom, PL6 8BX

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	◉	◉	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: September 23, 2009 (v17)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

	Related Macular Degeneration (AMD) (VIEW 2)
Official Title:	A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).
Secondary IDs:	EurdaCT No.: 2007-000583-25

Study Status

Record Verification:	September 2009
Overall Status:	Active, not recruiting
Study Start:	April 2008
Primary Completion:	July 2011 [Anticipated]
Study Completion:	September 2011 [Anticipated]
First Submitted:	March 12, 2008
First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	September 23, 2009
Last Update Posted:	September 24, 2009 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

Buenos Aires, Capital Federal, Argentina, C1015ABO

Buenos Aires, Capital Federal, Argentina, C1023AAQ

Buenos Aires, Capital Federal, Argentina, C1122AAI

Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

Córdoba, Argentina, X5000IIT

Australia, New South Wales

Chatswood, New South Wales, Australia, 2067

Sydney, New South Wales, Australia, 2000

Westmead, New South Wales, Australia, 2145

Australia, Victoria

East Melbourne, Victoria, Australia, 3002

Parkville, Victoria, Australia, 3050

Australia, Western Australia

Nedlands, Western Australia, Australia, 6009

Australia

Parramatta, Australia, 2150

Austria, Tirol

Innsbruck, Tirol, Austria, 6020

Austria

Linz, Austria, 4021

Wien, Austria, 1090

Belgium

Liege, Belgium, 4000

Brazil, SP

Araraquara, SP, Brazil, 14801-310

Sao Paulo, SP, Brazil, 04023-900

São Paulo, SP, Brazil, 05651-901

Brazil

Minas Gerais, Brazil, 30150-270

Colombia

Bogota, Colombia

Cali, Colombia

Medellín, Colombia

Czech Republic

Brno, Czech Republic, 62500

Olomouc, Czech Republic, 775 20

Praha 10, Czech Republic, 10034

Praha 4, Czech Republic, 14000

Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

Paris, Cedex 12, France, 75557

France

Besancon, France, 25030

Bordeaux, France, 33000

Dijon Cedex, France, BP 1542-21

Lyon, France, 69003

Lyon, France, 69006

Marseille, France, 13008

Nantes Cedex, France, 44035

Paris Cedex 10, France, 75475

Paris, France, 75015

Germany, Baden-Württemberg

Freiburg, Baden-Württemberg, Germany, 79106

Heidelberg, Baden-Württemberg, Germany, 69120

Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

München, Bayern, Germany, 81675

Regensburg, Bayern, Germany, 93053

Germany, Hessen

Darmstadt, Hessen, Germany, 64276

Germany, Nordrhein-Westfalen

Aachen, Nordrhein-Westfalen, Germany, 52074

Bonn, Nordrhein-Westfalen, Germany, 53105

Essen, Nordrhein-Westfalen, Germany, 45147

Köln, Nordrhein-Westfalen, Germany, 50931

Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

Ludwigshafen, Rheinland-Pfalz, Germany, 67063

Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

Homburg, Saarland, Germany, 66421

Germany, Sachsen

Dresden, Sachsen, Germany, 01067

Dresden, Sachsen, Germany, 01307

Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

Kiel, Schleswig-Holstein, Germany, 24105

Lübeck, Schleswig-Holstein, Germany, 23538

Germany

Berlin, Germany, 12200

Hamburg, Germany, 20251

Hungary

Budapest, Hungary, 1036

Budapest, Hungary, 1089

Budapest, Hungary, 1106

Veszprem, Hungary, 8200

India, Maharashtra

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

Chennai, Tamil Nadu, India, 600 006

Coimbatore, Tamil Nadu, India, 641014

Madurai, Tamil Nadu, India, 625 020

Pondicherry, Tamil Nadu, India, 600007

India

Bangalore, India, 560010

Chandigarh, India, 160062

Gugarat, India

Hyderabad, India, 500 034

Kerala, India, 683572

Kolkata, India, 700073

Mumbai, India, 400 050

New Delhi, India, 110002

New Delhi, India, 110029

Orissa, India, 751 024

Israel

Afula, Israel, 18101

Beer Sheva, Israel, 84101

Haifa, Israel, 34362

Jerusalem, Israel, 91120

Kfar Saba, Israel, 44281

Petach Tikva, Israel, 49100

Rehovot, Israel, 76100

Tel Aviv, Israel, 64239

Tel Hashomer, Israel, 52621

Zerifin, Israel, 70300

Italy

Ancona, Italy, 60020

Bari, Italy, 70124

Catania, Italy, 95123

Genova, Italy, 16132

Milano, Italy, 20132

Milano, Italy, 20142

Padova, Italy, 35128

Roma, Italy, 00133

Roma, Italy, 00168

Roma, Italy, 00185

Torino, Italy, 10126

Udine, Italy, 33100

Varese, Italy, 21100

Japan, Aichi

Nagoya, Aichi, Japan, 466-8560

Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

Kita, Kagawa, Japan, 761-0793

Japan, Osaka

Hirakata, Osaka, Japan, 573-1191

Suita, Osaka, Japan, 565-0871

Japan, Shiga

Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

Chiyoda-ku, Tokyo, Japan, 101-8309

Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

Fukuoka, Japan, 812-8582

Fukushima, Japan, 960-1295

Kagoshima, Japan, 890-8520

Kyoto, Japan, 606-8507

Korea, Republic of, Gyeonggi-do

Seongnam, Gyeonggi-do, Korea, Republic of, 463 707

Korea, Republic of, Korea

Seoul, Korea, Korea, Republic of, 110-744

Korea, Republic of

Incheon, Korea, Republic of, 405-760

Seoul, Korea, Republic of, 110 744

Seoul, Korea, Republic of, 138-736

Seoul, Korea, Republic of, 152-703

Latvia

Riga, Latvia, 1002

Riga, Latvia, 1009

Mexico, DF

Mexico City, DF, Mexico, 06800

Mexico, Jalisco

Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

Monterrey, Nuevo Leon, Mexico, 64060

Monterrey, Nuevo Leon, Mexico, 64460

Mexico

Chihuahua, Mexico, 31238

Mexico City, Mexico, 06030

México D.F., Mexico, 04030

Netherlands, EX

Nijmegen, EX, Netherlands, 6525

Netherlands

Groningen, Netherlands, 9713 GZ

Leiden, Netherlands, 2333 ZA

Rotterdam, Netherlands, 3015 GD

Poland

Bydgoszcz, Poland, 85-631

Gdansk, Poland, 80-952

Katowice, Poland, 40-760

Poznan, Poland, 60-355

Warszawa, Poland, 00-416

Warszawa, Poland, 02-005

Wroclaw, Poland, 50-368

Portugal

Coimbra, Portugal, 3000-548

Porto, Portugal, 4200-319

Singapore

Ask Contact, Singapore, 168751

Singapore, Singapore, 119074

Singapore, Singapore, 159964

Singapore, Singapore, 308433

Slovakia

Banska Bystrica, Slovakia, 97517

Bratislava, Slovakia, 813 69

Spain, Asturias

Oviedo, Asturias, Spain, 33012

Spain, La Coruna

Santiago de Compostela, La Coruna, Spain, 15705

Spain

Alicante, Spain, 03016

Barcelona, Spain, 08017

Barcelona, Spain, 08022

Barcelona, Spain, 08035

Barcelona, Spain, 08036

Madrid, Spain, 28002

Madrid, Spain, 28046

Malaga, Spain, 29010

Pamplona, Spain, 31008

Sevilla, Spain, 41013

Sevilla, Spain, 41071

Valencia, Spain, 46014

Valencia, Spain, 46015

Valladolid, Spain, 47005

Sweden

Linköping, Sweden, 58185

Stockholm, Sweden, 11282

Örebro, Sweden, 70185

Switzerland

Basel, Switzerland, 4031

Bern, Switzerland, 3010

Genève, Switzerland, 1211

Zürich, Switzerland, 8091

United Kingdom, Devon

Torbay, Devon, United Kingdom, TQ2 7AA

United Kingdom, Grampian

Aberdeen, Grampian, United Kingdom, AB25 2ZN

United Kingdom, Greater London

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Merseyside

Liverpool, Merseyside, United Kingdom, L7 8XP

United Kingdom, Northern Ireland

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Surrey

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

Birmingham, United Kingdom, B4 7ET

London, United Kingdom, NW1 5QH

Plymouth, United Kingdom, PL6 8BX

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	◉	◉	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: September 1, 2009 (v16)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

	Related Macular Degeneration (AMD) (VIEW 2)
Official Title:	A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).
Secondary IDs:	EurdaCT No.: 2007-000583-25

Study Status

Record Verification:	September 2009
Overall Status:	Recruiting
Study Start:	April 2008
Primary Completion:	July 2011 [Anticipated]
Study Completion:	September 2011 [Anticipated]
First Submitted:	March 12, 2008
First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	September 1, 2009
Last Update Posted:	September 2, 2009 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1122AAI

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Active, not recruiting]
Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

[Not yet recruiting]
Buenos Aires, Argentina

[Recruiting]
Córdoba, Argentina, X5000IIT

[Not yet recruiting]
Mendoza, Argentina, M5500GGK

Australia, New South Wales

[Recruiting]
Chatswood, New South Wales, Australia, 2067

[Recruiting]
Sydney, New South Wales, Australia, 2000

[Recruiting]
Westmead, New South Wales, Australia, 2145

Australia, Victoria

[Recruiting]
East Melbourne, Victoria, Australia, 3002

[Recruiting]
Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]
Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]
Parramatta, Australia, 2150

Austria, Tirol

[Recruiting]
Innsbruck, Tirol, Austria, 6020

Austria

[Recruiting]
Linz, Austria, 4021

[Recruiting]
Wien, Austria, 1090

Belgium

[Recruiting]
Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]
Goiania, Centro-oeste, Brazil, 74210-010

Brazil, SP

[Recruiting]
Araraquara, SP, Brazil, 14801-310

[Recruiting]
Sao Paulo, SP, Brazil, 04023-900

[Recruiting]
São Paulo, SP, Brazil, 05651-901

Brazil

[Recruiting]
Minas Gerais, Brazil, 30150-270

Colombia

[Recruiting]
Bogota, Colombia

[Recruiting]
Cali, Colombia

[Recruiting]
Medellín, Colombia

Czech Republic

[Recruiting]
Brno, Czech Republic, 62500

[Recruiting]
Olomouc, Czech Republic, 775 20

[Recruiting]
Praha 10, Czech Republic, 10034

[Recruiting]
Praha 4, Czech Republic, 14000

[Recruiting]
Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

[Recruiting]
Paris, Cedex 12, France, 75557

France

[Recruiting]
Besancon, France, 25030

[Recruiting]

Bordeaux, France, 33000

[Recruiting]

Dijon Cedex, France, BP 1542-21

[Recruiting]

Lyon, France, 69003

[Recruiting]

Lyon, France, 69006

[Recruiting]

Marseille, France, 13008

[Recruiting]

Nantes Cedex, France, 44035

[Recruiting]

Paris Cedex 10, France, 75475

[Recruiting]

Paris, France, 75015

Germany, Baden-Württemberg

[Recruiting]

Freiburg, Baden-Württemberg, Germany, 79106

[Recruiting]

Heidelberg, Baden-Württemberg, Germany, 69120

[Recruiting]

Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

[Recruiting]

München, Bayern, Germany, 81675

[Recruiting]

Regensburg, Bayern, Germany, 93053

Germany, Hessen

[Recruiting]
Darmstadt, Hessen, Germany, 64276

Germany, Niedersachsen

[Not yet recruiting]
Göttingen, Niedersachsen, Germany, 37075

Germany, Nordrhein-Westfalen

[Recruiting]
Aachen, Nordrhein-Westfalen, Germany, 52074

[Recruiting]
Bonn, Nordrhein-Westfalen, Germany, 53105

[Recruiting]
Essen, Nordrhein-Westfalen, Germany, 45147

[Recruiting]
Köln, Nordrhein-Westfalen, Germany, 50931

[Not yet recruiting]
Köln, Nordrhein-Westfalen, Germany, 51109

[Recruiting]
Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

[Recruiting]
Ludwigshafen, Rheinland-Pfalz, Germany, 67063

[Recruiting]
Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

[Recruiting]
Homburg, Saarland, Germany, 66421

Germany, Sachsen

[Recruiting]
Dresden, Sachsen, Germany, 01067

[Recruiting]
Dresden, Sachsen, Germany, 01307

[Recruiting]
Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

[Recruiting]
Kiel, Schleswig-Holstein, Germany, 24105

[Recruiting]
Lübeck, Schleswig-Holstein, Germany, 23538

Germany

[Recruiting]
Berlin, Germany, 12200

[Recruiting]
Hamburg, Germany, 20251

Hungary

[Recruiting]
Budapest, Hungary, 1036

[Recruiting]
Budapest, Hungary, 1089

[Recruiting]
Budapest, Hungary, 1106

[Recruiting]
Veszprem, Hungary, 8200

India, Maharashtra

[Recruiting]

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Recruiting]

Chennai, Tamil Nadu, India, 600 006

[Recruiting]

Coimbatore, Tamil Nadu, India, 641014

[Recruiting]

Madurai, Tamil Nadu, India, 625 020

[Recruiting]

Pondicherry, Tamil Nadu, India, 600007

India

[Recruiting]

Bangalore, India, 560010

[Recruiting]

Chandigarh, India, 160062

[Recruiting]

Gugarat, India

[Recruiting]

Hyderabad, India, 500 034

[Recruiting]

Kerala, India, 683572

[Recruiting]

Kolkata, India, 700073

[Recruiting]

Mumbai, India, 400 050

[Recruiting]

New Delhi, India, 110002

[Recruiting]
New Delhi, India, 110029

[Recruiting]
Orissa, India, 751 024

Israel

[Recruiting]
Afula, Israel, 18101

[Recruiting]
Beer Sheva, Israel, 84101

[Recruiting]
Haifa, Israel, 34362

[Recruiting]
Jerusalem, Israel, 91120

[Recruiting]
Kfar Saba, Israel, 44281

[Recruiting]
Petach Tikva, Israel, 49100

[Recruiting]
Rehovot, Israel, 76100

[Recruiting]
Tel Aviv, Israel, 64239

[Recruiting]
Tel Hashomer, Israel, 52621

[Recruiting]
Zerifin, Israel, 70300

Italy, Trieste

[Terminated]
Aurisina, Trieste, Italy, 34011

Italy

[Recruiting]
Ancona, Italy, 60020

[Recruiting]
Bari, Italy, 70124

[Recruiting]
Catania, Italy

[Not yet recruiting]
Firenze, Italy, 50139

[Recruiting]
Genova, Italy, 16132

[Recruiting]
Milano, Italy, 20132

[Not yet recruiting]
Milano, Italy, 20142

[Recruiting]
Milano, Italy, 20142

[Recruiting]
Padova, Italy, 35128

[Recruiting]
Roma, Italy, 00133

[Recruiting]
Roma, Italy, 00168

[Recruiting]
Roma, Italy, 00198

[Recruiting]
Torino, Italy, 10126

[Recruiting]

Udine, Italy, 33100

[Recruiting]
Varese, Italy, 21100

Japan, Aichi

[Recruiting]
Nagoya, Aichi, Japan, 466-8560

[Recruiting]
Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Recruiting]
Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Recruiting]
Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

[Recruiting]
Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Recruiting]
Kita, Kagawa, Japan, 761-0793

Japan, Osaka

[Recruiting]
Hirakata, Osaka, Japan, 573-1191

[Recruiting]
Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Recruiting]

Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Recruiting]
Chiyoda-ku, Tokyo, Japan, 101-8309

[Recruiting]
Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

[Recruiting]
Fukuoka, Japan, 812-8582

[Recruiting]
Fukushima, Japan, 960-1295

[Recruiting]
Kagoshima, Japan, 890-8520

[Recruiting]
Kyoto, Japan, 606-8507

Korea, Republic of, Gyeonggi-do

[Recruiting]
Seongnam, Gyeonggi-do, Korea, Republic of, 463 707

Korea, Republic of, Korea

[Recruiting]
Seoul, Korea, Korea, Republic of, 110 744

Korea, Republic of

[Recruiting]
Incheon, Korea, Republic of, 405-760

[Recruiting]
Seoul, Korea, Republic of, 110-744

[Recruiting]

Seoul, Korea, Republic of, 138-736

[Recruiting]
Seoul, Korea, Republic of, 152-703

Latvia

[Recruiting]
Riga, Latvia, 1002

[Recruiting]
Riga, Latvia, 1009

Mexico, DF

[Recruiting]
Mexico City, DF, Mexico, 06800

[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Jalisco

[Recruiting]
Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64060

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64460

Mexico

[Recruiting]
Chihuahua, Mexico, 31238

[Recruiting]
Mexico City, Mexico, 06030

[Recruiting]

México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]
Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Recruiting]
Nijmegen, EX, Netherlands, 6525

Netherlands

[Recruiting]
Groningen, Netherlands, 9713 GZ

[Recruiting]
Leiden, Netherlands, 2333 ZA

[Recruiting]
Rotterdam, Netherlands, 3015 GD

Poland

[Recruiting]
Bydgoszcz, Poland, 85-631

[Recruiting]
Gdansk, Poland, 80-952

[Recruiting]
Katowice, Poland, 40-760

[Recruiting]
Poznan, Poland, 60-355

[Recruiting]
Warszawa, Poland, 00-416

[Not yet recruiting]
Warszawa, Poland, 00-621

[Recruiting]
Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Recruiting]
Wroclaw, Poland, 50-368

Portugal

[Recruiting]
Coimbra, Portugal, 3000-548

[Not yet recruiting]
Lisboa, Portugal, 1649-035

[Recruiting]
Porto, Portugal, 4200-319

Singapore

[Recruiting]
Ask Contact, Singapore, 168751

[Recruiting]
Singapore, Singapore, 119074

[Recruiting]
Singapore, Singapore, 159964

[Recruiting]
Singapore, Singapore, 308433

Slovakia

[Recruiting]
Banska Bystrica, Slovakia, 97517

[Recruiting]
Bratislava, Slovakia, 813 69

Spain, Asturias

[Recruiting]
Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Recruiting]
Santiago de Compostela, La Coruna, Spain, 15705

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15706

Spain

[Recruiting]
Alicante, Spain, 03016

[Recruiting]
Barcelona, Spain, 08017

[Recruiting]
Barcelona, Spain, 08022

[Recruiting]
Barcelona, Spain, 08035

[Recruiting]
Barcelona, Spain, 08036

[Recruiting]
Madrid, Spain, 28002

[Recruiting]
Madrid, Spain, 28046

[Recruiting]
Malaga, Spain, 29010

[Recruiting]
Pamplona, Spain, 31008

[Recruiting]
Sevilla, Spain, 41013

[Recruiting]
Sevilla, Spain, 41071

[Recruiting]
Valencia, Spain, 46014

[Recruiting]
Valencia, Spain, 46015

[Recruiting]
Valladolid, Spain, 47005

Sweden

[Recruiting]
Linköping, Sweden, 58185

[Recruiting]
Stockholm, Sweden, 11282

[Recruiting]
Örebro, Sweden, 70185

Switzerland

[Recruiting]
Basel, Switzerland, 4031

[Recruiting]
Bern, Switzerland, 3010

[Recruiting]
Genève, Switzerland, 1211

[Recruiting]
Zürich, Switzerland, 8091

United Kingdom, Devon

[Recruiting]
Torbay, Devon, United Kingdom, TQ2 7AA

United Kingdom, Gloucestershire

[Not yet recruiting]

Gloucester, Gloucestershire, United Kingdom, GL1 3NN

United Kingdom, Grampian

[Recruiting]

Aberdeen, Grampian, United Kingdom, AB25 2ZN

United Kingdom, Greater London

[Recruiting]

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Recruiting]

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Merseyside

[Recruiting]

Liverpool, Merseyside, United Kingdom, L7 8XP

United Kingdom, Northern Ireland

[Recruiting]

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]

Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Recruiting]

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Recruiting]

Birmingham, United Kingdom, B4 7ET

[Not yet recruiting]

London, United Kingdom, EC1V 2PD

[Recruiting]

London, United Kingdom, NW1 5QH

[Not yet recruiting]

Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]

Oxford, United Kingdom, OX3 9DU

[Recruiting]

Plymouth, United Kingdom, PL6 8BX

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls | Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	◉	◉	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: July 3, 2009 (v15)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification: July 2009

Overall Status: Recruiting

Study Start: April 2008

Primary Completion: July 2011 [Anticipated]

Study Completion: September 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: July 3, 2009

Last Update Posted: July 7, 2009 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm&#xfffd;, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1122AAI

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Recruiting]
Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

[Not yet recruiting]
Buenos Aires, Argentina

[Recruiting]
Córdoba, Argentina, X5000IIT

[Not yet recruiting]
Mendoza, Argentina, M5500GGK

Australia, New South Wales

[Recruiting]
Chatswood, New South Wales, Australia, 2067

[Not yet recruiting]
Sydney, New South Wales, Australia, 2000

[Recruiting]
Westmead, New South Wales, Australia, 2145

Australia, Victoria

[Recruiting]
East Melbourne, Victoria, Australia, 3002

[Recruiting]
Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]
Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]
Parramatta, Australia, 2150

Austria, Steiermark

[Not yet recruiting]
Graz, Steiermark, Austria, 8036

Austria, Tirol

[Recruiting]
Innsbruck, Tirol, Austria, 6020

Austria

[Recruiting]
Linz, Austria, 4021

[Recruiting]
Wien, Austria, 1090

Belgium

[Not yet recruiting]
Bruxelles - Brussel, Belgium, 1020

[Recruiting]
Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]
Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]

Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Recruiting]
Araraquara, SP, Brazil, 14801-310

[Recruiting]
Sao Paulo, SP, Brazil, 04023-900

[Not yet recruiting]
São Paulo, SP, Brazil, 05651-901

Brazil

[Recruiting]
Minas Gerais, Brazil, 30150-270

Colombia

[Recruiting]
Bogota, Colombia

[Recruiting]
Cali, Colombia

[Recruiting]
Medellín, Colombia

Czech Republic

[Recruiting]
Brno, Czech Republic, 62500

[Recruiting]
Olomouc, Czech Republic, 775 20

[Not yet recruiting]
Praha 10, Czech Republic, 10034

[Recruiting]
Praha 4, Czech Republic, 14000

[Recruiting]

Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

[Recruiting]

Paris, Cedex 12, France, 75557

France

[Recruiting]

Besancon, France, 25030

[Recruiting]

Bordeaux, France, 33000

[Recruiting]

Dijon Cedex, France, BP 1542-21

[Not yet recruiting]

Grenoble, France, 38043

[Recruiting]

Lyon, France, 69003

[Recruiting]

Lyon, France, 69006

[Recruiting]

Marseille, France, 13008

[Recruiting]

Nantes Cedex, France, 44035

[Recruiting]

Paris Cedex 10, France, 75475

[Recruiting]

Paris, France, 75015

Germany, Baden-Württemberg

[Recruiting]

Freiburg, Baden-Württemberg, Germany, 79106

[Recruiting]
Heidelberg, Baden-Württemberg, Germany, 69120

[Recruiting]
Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

[Recruiting]
München, Bayern, Germany, 81675

[Recruiting]
Regensburg, Bayern, Germany, 93053

Germany, Hessen

[Not yet recruiting]
Darmstadt, Hessen, Germany, 64276

[Not yet recruiting]
Marburg, Hessen, Germany, 35043

Germany, Niedersachsen

[Not yet recruiting]
Göttingen, Niedersachsen, Germany, 37075

Germany, Nordrhein-Westfalen

[Recruiting]
Aachen, Nordrhein-Westfalen, Germany, 52074

[Recruiting]
Bonn, Nordrhein-Westfalen, Germany, 53105

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40219

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40225

[Recruiting]
Essen, Nordrhein-Westfalen, Germany, 45147

[Recruiting]
Köln, Nordrhein-Westfalen, Germany, 50931

[Not yet recruiting]
Köln, Nordrhein-Westfalen, Germany, 51109

[Recruiting]
Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

[Not yet recruiting]
Ludwigshafen, Rheinland-Pfalz, Germany, 67063

[Recruiting]
Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

[Recruiting]
Homburg, Saarland, Germany, 66421

Germany, Sachsen

[Not yet recruiting]
Dresden, Sachsen, Germany, 01067

[Recruiting]
Dresden, Sachsen, Germany, 01307

[Recruiting]
Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

[Recruiting]
Kiel, Schleswig-Holstein, Germany, 24105

[Not yet recruiting]
Lübeck, Schleswig-Holstein, Germany, 23538

Germany

[Not yet recruiting]
Berlin, Germany, 12200

[Recruiting]
Hamburg, Germany, 20251

Hungary

[Recruiting]
Budapest, Hungary, 1036

[Recruiting]
Budapest, Hungary, 1089

[Recruiting]
Budapest, Hungary, 1106

[Recruiting]
Veszprem, Hungary, 8200

India, Maharashtra

[Recruiting]
Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Recruiting]
Chennai, Tamil Nadu, India, 600 006

[Recruiting]
Coimbatore, Tamil Nadu, India, 641014

[Recruiting]
Madurai, Tamil Nadu, India, 625 020

[Recruiting]
Pondicherry, Tamil Nadu, India, 600007

India

[Recruiting]
Bangalore, India, 560010

[Recruiting]
Chandigarh, India, 160062

[Recruiting]
Gugarat, India

[Recruiting]
Hyderabad, India, 500 034

[Recruiting]
Kerala, India, 683572

[Recruiting]
Kolkata, India, 700073

[Recruiting]
Mumbai, India, 400 050

[Recruiting]
New Delhi, India, 110002

[Recruiting]
New Delhi, India, 110029

[Recruiting]
Orissa, India, 751 024

Israel

[Recruiting]
Afula, Israel, 18101

[Not yet recruiting]
Beer Sheva, Israel, 84101

[Recruiting]
Haifa, Israel, 34362

[Recruiting]

Jerusalem, Israel, 91120

[Recruiting]
Kfar Saba, Israel, 44281

[Recruiting]
Petach Tikva, Israel, 49100

[Recruiting]
Rehovot, Israel, 76100

[Recruiting]
Tel Aviv, Israel, 64239

[Recruiting]
Tel Hashomer, Israel, 52621

[Recruiting]
Zerifin, Israel, 70300

Italy

[Recruiting]
Ancona, Italy, 60020

[Recruiting]
Bari, Italy, 70124

[Recruiting]
Catania, Italy

[Not yet recruiting]
Firenze, Italy, 50139

[Recruiting]
Genova, Italy, 16132

[Recruiting]
Milano, Italy, 20132

[Not yet recruiting]
Milano, Italy, 20142

[Recruiting]
Milano, Italy, 20142

[Not yet recruiting]
Padova, Italy, 35128

[Recruiting]
Roma, Italy, 00133

[Not yet recruiting]
Roma, Italy, 00168

[Recruiting]
Roma, Italy, 00198

[Not yet recruiting]
Siena, Italy, 53100

[Recruiting]
Torino, Italy, 10126

[Recruiting]
Udine, Italy, 33100

[Not yet recruiting]
Varese, Italy, 21100

Japan, Aichi

[Recruiting]
Nagoya, Aichi, Japan, 466-8560

[Recruiting]
Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Recruiting]
Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Recruiting]

Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

[Recruiting]
Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Recruiting]
Kita, Kagawa, Japan, 761-0793

Japan, Osaka

[Recruiting]
Hirakata, Osaka, Japan, 573-1191

[Recruiting]
Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Recruiting]
Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Recruiting]
Chiyoda-ku, Tokyo, Japan, 101-8309

[Recruiting]
Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

[Recruiting]
Fukuoka, Japan, 812-8582

[Recruiting]
Fukushima, Japan, 960-1295

[Recruiting]
Kagoshima, Japan, 890-8520

[Recruiting]

Kyoto, Japan, 606-8507

Korea, Republic of, Gyeonggi-do

[Recruiting]

Seongnam, Gyeonggi-do, Korea, Republic of, 463 707

Korea, Republic of, Korea

[Recruiting]

Seoul, Korea, Korea, Republic of, 110 744

Korea, Republic of

[Not yet recruiting]

Incheon, Korea, Republic of, 405-760

[Recruiting]

Seoul, Korea, Republic of, 110-744

[Recruiting]

Seoul, Korea, Republic of, 138-736

[Recruiting]

Seoul, Korea, Republic of, 152-703

Latvia

[Recruiting]

Riga, Latvia, 1002

[Recruiting]

Riga, Latvia, 1009

Mexico, DF

[Recruiting]

Mexico City, DF, Mexico, 06800

[Not yet recruiting]

Mexico City, DF, Mexico, 14080

Mexico, Jalisco

[Recruiting]
Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64060

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64460

Mexico

[Recruiting]
Chihuahua, Mexico, 31238

[Recruiting]
Mexico City, Mexico, 06030

[Recruiting]
México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]
Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Recruiting]
Nijmegen, EX, Netherlands, 6525

Netherlands

[Recruiting]
Groningen, Netherlands, 9713 GZ

[Recruiting]
Leiden, Netherlands, 2333 ZA

[Recruiting]

Rotterdam, Netherlands, 3015 GD

Poland

[Recruiting]
Bydgoszcz, Poland, 85-631

[Recruiting]
Gdansk, Poland, 80-952

[Recruiting]
Katowice, Poland, 40-760

[Recruiting]
Poznan, Poland, 60-355

[Not yet recruiting]
Warszawa, Poland, 00-416

[Not yet recruiting]
Warszawa, Poland, 00-621

[Recruiting]
Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Recruiting]
Wroclaw, Poland, 50-368

Portugal

[Recruiting]
Coimbra, Portugal, 3000-548

[Not yet recruiting]
Lisboa, Portugal, 1649-035

[Recruiting]
Porto, Portugal, 4200-319

Singapore

[Recruiting]
Singapore, Singapore, 119074

[Recruiting]
Singapore, Singapore, 159964

[Recruiting]
Singapore, Singapore, 168751

[Recruiting]
Singapore, Singapore, 308433

Slovakia

[Recruiting]
Banska Bystrica, Slovakia, 97517

[Recruiting]
Bratislava, Slovakia, 813 69

Spain, Asturias

[Recruiting]
Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Recruiting]
Santiago de Compostela, La Coruna, Spain, 15705

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15706

Spain

[Recruiting]
Alicante, Spain, 03016

[Recruiting]
Barcelona, Spain, 08017

[Recruiting]

Barcelona, Spain, 08022

[Not yet recruiting]
Barcelona, Spain, 08035

[Recruiting]
Barcelona, Spain, 08036

[Recruiting]
Madrid, Spain, 28002

[Recruiting]
Madrid, Spain, 28046

[Recruiting]
Malaga, Spain, 29010

[Recruiting]
Pamplona, Spain, 31008

[Recruiting]
Sevilla, Spain, 41013

[Recruiting]
Sevilla, Spain, 41071

[Not yet recruiting]
Valencia, Spain, 46014

[Recruiting]
Valencia, Spain, 46015

[Recruiting]
Valladolid, Spain, 47005

Sweden

[Recruiting]
Linköping, Sweden, 58185

[Recruiting]
Stockholm, Sweden, 11282

[Recruiting]

Örebro, Sweden, 70185

Switzerland

[Recruiting]

Basel, Switzerland, 4031

[Recruiting]

Bern, Switzerland, 3010

[Recruiting]

Genève, Switzerland, 1211

[Recruiting]

Zürich, Switzerland, 8091

United Kingdom, Devon

[Recruiting]

Torbay, Devon, United Kingdom, TQ2 7AA

United Kingdom, Gloucestershire

[Not yet recruiting]

Gloucester, Gloucestershire, United Kingdom, GL1 3NN

United Kingdom, Grampian

[Recruiting]

Aberdeen, Grampian, United Kingdom, AB25 2ZN

United Kingdom, Greater London

[Recruiting]

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Recruiting]

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Merseyside

[Recruiting]
Liverpool, Merseyside, United Kingdom, L7 8XP

United Kingdom, Northern Ireland

[Recruiting]
Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]
Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Recruiting]
Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Recruiting]
Birmingham, United Kingdom, B4 7ET

[Not yet recruiting]
Dorchester, United Kingdom, DT1 2JY

[Not yet recruiting]
London, United Kingdom, EC1V 2PD

[Recruiting]
London, United Kingdom, NW1 5QH

[Terminated]
Manchester, United Kingdom, M13 9PT

[Not yet recruiting]
Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]
Oxford, United Kingdom, OX3 9DU

[Recruiting]
Plymouth, United Kingdom, PL6 8BX

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	◉	◉	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: June 4, 2009 (v14)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification: June 2009

Overall Status: Recruiting

Study Start: April 2008

Primary Completion: July 2011 [Anticipated]

Study Completion: September 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: June 4, 2009

Last Update Posted: June 5, 2009 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1122AAI

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Recruiting]
Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

[Not yet recruiting]
Buenos Aires, Argentina

[Recruiting]
Córdoba, Argentina, X5000IIT

[Not yet recruiting]
Mendoza, Argentina, M5500GGK

Australia, New South Wales

[Recruiting]
Chatswood, New South Wales, Australia, 2067

[Not yet recruiting]
Sydney, New South Wales, Australia, 2000

[Recruiting]
Westmead, New South Wales, Australia, 2145

Australia, Victoria

[Recruiting]
East Melbourne, Victoria, Australia, 3002

[Recruiting]
Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]
Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]
Parramatta, Australia, 2150

Austria, Steiermark

[Not yet recruiting]
Graz, Steiermark, Austria, 8036

Austria, Tirol

[Recruiting]
Innsbruck, Tirol, Austria, 6020

Austria

[Not yet recruiting]
Linz, Austria, 4021

[Recruiting]
Wien, Austria, 1090

Belgium

[Not yet recruiting]
Bruxelles - Brussel, Belgium, 1020

[Recruiting]
Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]
Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]

Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Not yet recruiting]
Araraquara, SP, Brazil, 14801-310

[Recruiting]
Sao Paulo, SP, Brazil, 04023-900

[Not yet recruiting]
São Paulo, SP, Brazil, 05651-901

Brazil

[Not yet recruiting]
Minas Gerais, Brazil, 30150-270

Colombia

[Recruiting]
Bogota, Colombia

[Recruiting]
Cali, Colombia

[Recruiting]
Medellín, Colombia

Czech Republic

[Recruiting]
Brno, Czech Republic, 62500

[Recruiting]
Olomouc, Czech Republic, 775 20

[Not yet recruiting]
Praha 10, Czech Republic, 10034

[Recruiting]
Praha 4, Czech Republic, 14000

[Not yet recruiting]
Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

[Recruiting]
Paris, Cedex 12, France, 75557

France

[Not yet recruiting]
Besancon, France, 25030

[Recruiting]
Bordeaux, France, 33000

[Recruiting]
Dijon Cedex, France, BP 1542-21

[Not yet recruiting]
Grenoble, France, 38043

[Recruiting]
Lyon, France, 69003

[Recruiting]
Lyon, France, 69006

[Recruiting]
Marseille, France, 13008

[Recruiting]
Nantes Cedex, France, 44035

[Recruiting]
Paris Cedex 10, France, 75475

[Recruiting]
Paris, France, 75015

Germany, Baden-Württemberg

[Recruiting]

Freiburg, Baden-Württemberg, Germany, 79106

[Recruiting]
Heidelberg, Baden-Württemberg, Germany, 69120

[Recruiting]
Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

[Recruiting]
München, Bayern, Germany, 81675

[Not yet recruiting]
Regensburg, Bayern, Germany, 93053

Germany, Hessen

[Not yet recruiting]
Darmstadt, Hessen, Germany, 64276

[Not yet recruiting]
Marburg, Hessen, Germany, 35043

Germany, Niedersachsen

[Not yet recruiting]
Göttingen, Niedersachsen, Germany, 37075

Germany, Nordrhein-Westfalen

[Recruiting]
Aachen, Nordrhein-Westfalen, Germany, 52074

[Recruiting]
Bonn, Nordrhein-Westfalen, Germany, 53105

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40219

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40225

[Not yet recruiting]
Essen, Nordrhein-Westfalen, Germany, 45147

[Recruiting]
Köln, Nordrhein-Westfalen, Germany, 50931

[Not yet recruiting]
Köln, Nordrhein-Westfalen, Germany, 51109

[Recruiting]
Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

[Not yet recruiting]
Ludwigshafen, Rheinland-Pfalz, Germany, 67063

[Recruiting]
Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

[Recruiting]
Homburg, Saarland, Germany, 66421

Germany, Sachsen

[Not yet recruiting]
Dresden, Sachsen, Germany, 01067

[Recruiting]
Dresden, Sachsen, Germany, 01307

[Recruiting]
Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

[Recruiting]
Kiel, Schleswig-Holstein, Germany, 24105

[Not yet recruiting]
Lübeck, Schleswig-Holstein, Germany, 23538

Germany

[Not yet recruiting]
Berlin, Germany, 12200

[Recruiting]
Hamburg, Germany, 20251

Hungary

[Recruiting]
Budapest, Hungary, 1036

[Recruiting]
Budapest, Hungary, 1089

[Recruiting]
Budapest, Hungary, 1106

[Recruiting]
Veszprem, Hungary, 8200

India, Maharashtra

[Recruiting]
Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Recruiting]
Chennai, Tamil Nadu, India, 600 006

[Recruiting]
Coimbatore, Tamil Nadu, India, 641014

[Recruiting]
Madurai, Tamil Nadu, India, 625 020

[Recruiting]
Pondicherry, Tamil Nadu, India, 600007

India

[Recruiting]
Bangalore, India, 560010

[Recruiting]
Chandigarh, India, 160062

[Recruiting]
Gugarat, India

[Recruiting]
Hyderabad, India, 500 034

[Recruiting]
Kerala, India, 683572

[Recruiting]
Kolkata, India, 700073

[Recruiting]
Mumbai, India, 400 050

[Recruiting]
New Delhi, India, 110002

[Recruiting]
New Delhi, India, 110029

[Recruiting]
Orissa, India, 751 024

Israel

[Recruiting]
Afula, Israel, 18101

[Not yet recruiting]
Beer Sheva, Israel, 84101

[Not yet recruiting]
Haifa, Israel, 34362

[Recruiting]

Jerusalem, Israel, 91120

[Recruiting]
Kfar Saba, Israel, 44281

[Recruiting]
Petach Tikva, Israel, 49100

[Recruiting]
Rehovot, Israel, 76100

[Recruiting]
Tel Aviv, Israel, 64239

[Recruiting]
Tel Hashomer, Israel, 52621

[Recruiting]
Zerifin, Israel, 70300

Italy

[Recruiting]
Ancona, Italy, 60020

[Not yet recruiting]
Bari, Italy, 70124

[Terminated]
Bologna, Italy, 40133

[Not yet recruiting]
Catania, Italy

[Not yet recruiting]
Firenze, Italy, 50139

[Recruiting]
Genova, Italy, 16132

[Recruiting]
Milano, Italy, 20132

[Not yet recruiting]
Milano, Italy, 20142

[Recruiting]
Milano, Italy, 20142

[Not yet recruiting]
Padova, Italy, 35128

[Recruiting]
Roma, Italy, 00133

[Not yet recruiting]
Roma, Italy, 00168

[Recruiting]
Roma, Italy, 00198

[Not yet recruiting]
Siena, Italy, 53100

[Recruiting]
Torino, Italy, 10126

[Terminated]
Trieste, Italy, 34100

[Not yet recruiting]
Udine, Italy, 33100

[Not yet recruiting]
Varese, Italy, 21100

[Terminated]
Verona, Italy, 37121

Japan, Aichi

[Recruiting]
Nagoya, Aichi, Japan, 466-8560

[Recruiting]

Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Recruiting]
Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Recruiting]
Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

[Recruiting]
Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Recruiting]
Kita, Kagawa, Japan, 761-0793

Japan, Osaka

[Recruiting]
Hirakata, Osaka, Japan, 573-1191

[Recruiting]
Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Recruiting]
Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Recruiting]
Chiyoda-ku, Tokyo, Japan, 101-8309

[Recruiting]
Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

[Recruiting]

Fukuoka, Japan, 812-8582

[Recruiting]

Fukushima, Japan, 960-1295

[Recruiting]

Kagoshima, Japan, 890-8520

[Recruiting]

Kyoto, Japan, 606-8507

Korea, Republic of, Gyeonggi-do

[Not yet recruiting]

Seongnam, Gyeonggi-do, Korea, Republic of, 463 707

Korea, Republic of, Korea

[Not yet recruiting]

Seoul, Korea, Korea, Republic of, 110-744

Korea, Republic of

[Not yet recruiting]

Incheon, Korea, Republic of, 405-760

[Not yet recruiting]

Seoul, Korea, Republic of, 110 744

[Recruiting]

Seoul, Korea, Republic of, 138-736

[Not yet recruiting]

Seoul, Korea, Republic of, 152-703

Latvia

[Recruiting]

Riga, Latvia, 1002

[Recruiting]

Riga, Latvia, 1009

Mexico, DF

[Recruiting]
Mexico City, DF, Mexico, 06800

[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Jalisco

[Recruiting]
Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64060

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64460

Mexico

[Recruiting]
Chihuahua, Mexico, 31238

[Recruiting]
Mexico City, Mexico, 06030

[Recruiting]
México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]
Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Recruiting]
Nijmegen, EX, Netherlands, 6525

Netherlands

[Not yet recruiting]
Groningen, Netherlands, 9713 GZ

[Recruiting]
Leiden, Netherlands, 2333 ZA

[Recruiting]
Rotterdam, Netherlands, 3015 GD

Poland

[Not yet recruiting]
Bydgoszcz, Poland, 85-631

[Recruiting]
Gdansk, Poland, 80-952

[Recruiting]
Katowice, Poland, 40-760

[Not yet recruiting]
Poznan, Poland, 60-355

[Not yet recruiting]
Warszawa, Poland, 00-416

[Not yet recruiting]
Warszawa, Poland, 00-621

[Recruiting]
Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Recruiting]
Wroclaw, Poland, 50-368

Portugal

[Recruiting]
Coimbra, Portugal, 3000-548

[Not yet recruiting]
Lisboa, Portugal, 1649-035

[Recruiting]
Porto, Portugal, 4200-319

Singapore

[Recruiting]
Singapore, Singapore, 119074

[Not yet recruiting]
Singapore, Singapore, 159964

[Recruiting]
Singapore, Singapore, 168751

[Recruiting]
Singapore, Singapore, 308433

Slovakia

[Recruiting]
Banska Bystrica, Slovakia, 97517

[Recruiting]
Bratislava, Slovakia, 813 69

Spain, Asturias

[Recruiting]
Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Recruiting]
Santiago de Compostela, La Coruna, Spain, 15705

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15706

Spain

[Recruiting]
Alicante, Spain, 03016

[Recruiting]
Barcelona, Spain, 08017

[Not yet recruiting]
Barcelona, Spain, 08022

[Not yet recruiting]
Barcelona, Spain, 08035

[Not yet recruiting]
Barcelona, Spain, 08036

[Recruiting]
Madrid, Spain, 28002

[Not yet recruiting]
Madrid, Spain, 28046

[Recruiting]
Malaga, Spain, 29010

[Recruiting]
Pamplona, Spain, 31008

[Recruiting]
Sevilla, Spain, 41013

[Not yet recruiting]
Sevilla, Spain, 41071

[Not yet recruiting]
Valencia, Spain, 46014

[Not yet recruiting]
Valencia, Spain, 46015

[Recruiting]
Valladolid, Spain, 47005

Sweden

[Recruiting]
Linköping, Sweden, 58185

[Recruiting]
Stockholm, Sweden, 11282

[Recruiting]
Örebro, Sweden, 70185

Switzerland

[Recruiting]
Basel, Switzerland, 4031

[Recruiting]
Bern, Switzerland, 3010

[Not yet recruiting]
Genève, Switzerland, 1211

[Recruiting]
Zürich, Switzerland, 8091

United Kingdom, Devon

[Recruiting]
Torbay, Devon, United Kingdom, TQ2 7AA

United Kingdom, Gloucestershire

[Not yet recruiting]
Gloucester, Gloucestershire, United Kingdom, GL1 3NN

United Kingdom, Grampian

[Recruiting]
Aberdeen, Grampian, United Kingdom, AB25 2ZN

United Kingdom, Greater London

[Recruiting]

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Recruiting]
Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Merseyside

[Recruiting]
Liverpool, Merseyside, United Kingdom, L7 8XP

United Kingdom, Northern Ireland

[Recruiting]
Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]
Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Recruiting]
Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Recruiting]
Birmingham, United Kingdom, B4 7ET

[Not yet recruiting]
Dorchester, United Kingdom, DT1 2JY

[Not yet recruiting]
London, United Kingdom, EC1V 2PD

[Recruiting]
London, United Kingdom, NW1 5QH

[Not yet recruiting]
Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]
Oxford, United Kingdom, OX3 9DU

[Recruiting]
Plymouth, United Kingdom, PL6 8BX

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	◉	◉	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: May 4, 2009 (v13)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification: May 2009

Overall Status: Recruiting

Study Start: April 2008

Primary Completion: July 2011 [Anticipated]

Study Completion: July 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: May 4, 2009

Last Update Posted: May 5, 2009 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm&#xfffd;, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Buenos Aires**

[Terminated]
Olivos, Buenos Aires, Argentina, B1636CSS

Argentina, Capital Federal

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Terminated]
Buenos Aires, Capital Federal, Argentina, C1120AAN

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1122AAI

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Recruiting]
Rosario, Santa Fe, Argentina, S2000ANJ

Argentina, Tucumán

[Terminated]
San Miguel de Tucumán, Tucumán, Argentina, 4000

Argentina

[Not yet recruiting]
Buenos Aires, Argentina

[Terminated]
Córdoba, Argentina, 5000

[Recruiting]
Córdoba, Argentina, X5000IIT

[Not yet recruiting]
Mendoza, Argentina, M5500GGK

Australia, New South Wales

[Recruiting]
Chatswood, New South Wales, Australia, 2067

[Not yet recruiting]
Sydney, New South Wales, Australia, 2000

[Recruiting]
Westmead, New South Wales, Australia, 2145

Australia, South Australia

[Terminated]
Adelaide, South Australia, Australia, 5043

Australia, Victoria

[Recruiting]
East Melbourne, Victoria, Australia, 3002

[Recruiting]
Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]
Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]
Parramatta, Australia, 2150

Austria, Steiermark

[Not yet recruiting]
Graz, Steiermark, Austria, 8036

Austria, Tirol

[Recruiting]
Innsbruck, Tirol, Austria, 6020

Austria

[Not yet recruiting]
Linz, Austria, 4021

[Terminated]
Salzburg, Austria, 5020

[Recruiting]
Wien, Austria, 1090

[Terminated]
Wien, Austria, 1180

Belgium

[Not yet recruiting]
Bruxelles - Brussel, Belgium, 1020

[Terminated]
Bruxelles - Brussel, Belgium, 1070

[Terminated]
Gent, Belgium, 9000

[Terminated]
Leuven, Belgium, 3000

[Recruiting]
Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]
Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]
Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Not yet recruiting]
Araraquara, SP, Brazil, 14801-310

[Recruiting]

Sao Paulo, SP, Brazil, 04023-900

[Not yet recruiting]

São Paulo, SP, Brazil, 05651-901

Brazil

[Terminated]

Florianopolis, Brazil, 88015-080

[Not yet recruiting]

Minas Gerais, Brazil, 30150-270

Colombia

[Recruiting]

Bogota, Colombia

[Terminated]

Bogotá, Colombia

[Recruiting]

Cali, Colombia

[Terminated]

Floridablanca-Santander, Colombia

[Not yet recruiting]

Medellín, Colombia

[Terminated]

Medellín, Colombia

[Recruiting]

Medellín, Colombia

Czech Republic

[Recruiting]

Brno, Czech Republic, 62500

[Terminated]
Hradec Kralove, Czech Republic, 500 05

[Recruiting]
Olomouc, Czech Republic, 775 20

[Not yet recruiting]
Praha 10, Czech Republic, 10034

[Terminated]
Praha 2, Czech Republic, 12808

[Recruiting]
Praha 4, Czech Republic, 14000

[Not yet recruiting]
Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

[Recruiting]
Paris, Cedex 12, France, 75557

France

[Not yet recruiting]
Besancon, France, 25030

[Recruiting]
Bordeaux, France, 33000

[Recruiting]
Dijon Cedex, France, BP 1542-21

[Not yet recruiting]
Grenoble, France, 38043

[Recruiting]
Lyon, France, 69003

[Recruiting]
Lyon, France, 69006

[Recruiting]
Marseille, France, 13008

[Terminated]
Montpellier, France, 34295

[Recruiting]
Nantes Cedex, France, 44035

[Recruiting]
Paris Cedex 10, France, 75475

[Recruiting]
Paris, France, 75015

Germany, Baden-Württemberg

[Recruiting]
Freiburg, Baden-Württemberg, Germany, 79106

[Recruiting]
Heidelberg, Baden-Württemberg, Germany, 69120

[Recruiting]
Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

[Terminated]
Erlangen, Bayern, Germany, 91054

[Recruiting]
München, Bayern, Germany, 81675

[Not yet recruiting]
Regensburg, Bayern, Germany, 93053

Germany, Hessen

[Not yet recruiting]
Darmstadt, Hessen, Germany, 64276

Germany, Niedersachsen

[Not yet recruiting]
Göttingen, Niedersachsen, Germany, 37075

Germany, Nordrhein-Westfalen

[Recruiting]
Aachen, Nordrhein-Westfalen, Germany, 52074

[Recruiting]
Bonn, Nordrhein-Westfalen, Germany, 53105

[Terminated]
Duisburg, Nordrhein-Westfalen, Germany, 47119

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40219

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40225

[Not yet recruiting]
Essen, Nordrhein-Westfalen, Germany, 45147

[Recruiting]
Köln, Nordrhein-Westfalen, Germany, 50931

[Terminated]
Köln, Nordrhein-Westfalen, Germany, 50996

[Not yet recruiting]
Köln, Nordrhein-Westfalen, Germany, 51109

[Recruiting]
Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

[Not yet recruiting]
Ludwigshafen, Rheinland-Pfalz, Germany, 67063

[Recruiting]
Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

[Not yet recruiting]
Homburg, Saarland, Germany, 66421

[Terminated]
Sulzbach, Saarland, Germany, 66280

Germany, Sachsen

[Not yet recruiting]
Dresden, Sachsen, Germany, 01067

[Recruiting]
Dresden, Sachsen, Germany, 01307

[Recruiting]
Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

[Recruiting]
Kiel, Schleswig-Holstein, Germany, 24105

[Not yet recruiting]
Lübeck, Schleswig-Holstein, Germany, 23538

Germany

[Not yet recruiting]
Berlin, Germany, 12200

[Terminated]
Berlin, Germany, 13125

[Recruiting]
Hamburg, Germany, 20251

Hungary

[Recruiting]
Budapest, Hungary, 1036

[Recruiting]

Budapest, Hungary, 1089

[Recruiting]

Budapest, Hungary, 1106

[Recruiting]

Veszprem, Hungary, 8200

India, Maharashtra

[Recruiting]

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Recruiting]

Chennai, Tamil Nadu, India, 600 006

[Recruiting]

Coimbatore, Tamil Nadu, India, 641014

[Recruiting]

Madurai, Tamil Nadu, India, 625 020

[Recruiting]

Pondicherry, Tamil Nadu, India, 600007

India

[Recruiting]

Bangalore, India, 560010

[Recruiting]

Chandigarh, India, 160062

[Recruiting]

Gugarat, India

[Recruiting]

Hyderabad, India, 500 034

[Recruiting]

Kerala, India, 683572

[Recruiting]
Kolkata, India, 700073

[Recruiting]
Mumbai, India, 400 050

[Recruiting]
New Delhi, India, 110002

[Recruiting]
New Delhi, India, 110029

[Recruiting]
Orissa, India, 751 024

Israel

[Recruiting]
Afula, Israel, 18101

[Not yet recruiting]
Beer Sheva, Israel, 84101

[Not yet recruiting]
Haifa, Israel, 34362

[Recruiting]
Jerusalem, Israel, 91120

[Recruiting]
Kfar Saba, Israel, 44281

[Recruiting]
Petach Tikva, Israel, 49100

[Recruiting]
Rehovot, Israel, 76100

[Recruiting]
Tel Aviv, Israel, 64239

[Recruiting]
Tel Hashomer, Israel, 52621

[Recruiting]
Zerifin, Israel, 70300

Italy

[Not yet recruiting]
Ancona, Italy, 60020

[Not yet recruiting]
Bari, Italy, 70124

[Terminated]
Bologna, Italy, 40133

[Not yet recruiting]
Catania, Italy

[Not yet recruiting]
Firenze, Italy, 50139

[Recruiting]
Genova, Italy, 16132

[Recruiting]
Milano, Italy, 20132

[Not yet recruiting]
Milano, Italy, 20142

[Recruiting]
Milano, Italy, 20142

[Not yet recruiting]
Padova, Italy, 35128

[Recruiting]
Roma, Italy, 00133

[Not yet recruiting]

Roma, Italy, 00168

[Recruiting]
Roma, Italy, 00198

[Not yet recruiting]
Siena, Italy, 53100

[Not yet recruiting]
Torino, Italy, 10126

[Terminated]
Trieste, Italy, 34100

[Not yet recruiting]
Udine, Italy, 33100

[Not yet recruiting]
Varese, Italy, 21100

[Terminated]
Verona, Italy, 37121

Japan, Aichi

[Recruiting]
Nagoya, Aichi, Japan, 466-8560

[Recruiting]
Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Recruiting]
Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Recruiting]
Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

[Recruiting]

Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Recruiting]

Kita, Kagawa, Japan, 761-0793

Japan, Osaka

[Recruiting]

Hirakata, Osaka, Japan, 573-1191

[Recruiting]

Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Recruiting]

Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Recruiting]

Chiyoda-ku, Tokyo, Japan, 101-8309

[Recruiting]

Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

[Recruiting]

Fukuoka, Japan, 812-8582

[Recruiting]

Fukushima, Japan, 960-1295

[Recruiting]

Kagoshima, Japan, 890-8520

[Recruiting]

Kyoto, Japan, 606-8507

Korea, Republic of, Gyeonggi-do

[Not yet recruiting]
Seongnam, Gyeonggi-do, Korea, Republic of, 463 707

Korea, Republic of, Korea

[Not yet recruiting]
Seoul, Korea, Korea, Republic of, 110-744

Korea, Republic of

[Not yet recruiting]
Incheon, Korea, Republic of, 405-760

[Not yet recruiting]
Seoul, Korea, Republic of, 110 744

[Not yet recruiting]
Seoul, Korea, Republic of, 138-736

[Not yet recruiting]
Seoul, Korea, Republic of, 152-703

Latvia

[Recruiting]
Riga, Latvia, 1002

[Recruiting]
Riga, Latvia, 1009

[Terminated]
Riga, Latvia

Mexico, DF

[Recruiting]
Mexico City, DF, Mexico, 06800

[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Estado de México

[Terminated]
Metepec, Estado de México, Mexico, 52140

Mexico, Jalisco

[Recruiting]
Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64060

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64460

Mexico

[Not yet recruiting]
Chihuahua, Mexico, 31238

[Not yet recruiting]
Mexico City, Mexico, 06030

[Recruiting]
México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]
Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Recruiting]
Nijmegen, EX, Netherlands, 6525

Netherlands, Noord Brabant

[Terminated]
Eindhoven, Noord Brabant, Netherlands, 5623 EJ

Netherlands

[Not yet recruiting]
Groningen, Netherlands, 9713 GZ

[Recruiting]
Leiden, Netherlands, 2333 ZA

[Recruiting]
Rotterdam, Netherlands, 3015 GD

Poland

[Not yet recruiting]
Bydgoszcz, Poland, 85-631

[Recruiting]
Gdansk, Poland, 80-952

[Recruiting]
Katowice, Poland, 40-760

[Not yet recruiting]
Poznan, Poland, 60-355

[Terminated]
Sosnowiec, Poland, 41-200

[Not yet recruiting]
Warszawa, Poland, 00-416

[Not yet recruiting]
Warszawa, Poland, 00-621

[Terminated]
Warszawa, Poland, 01-755

[Recruiting]
Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Recruiting]
Wroclaw, Poland, 50-368

Portugal

[Recruiting]
Coimbra, Portugal, 3000-548

[Not yet recruiting]
Lisboa, Portugal, 1649-035

[Not yet recruiting]
Porto, Portugal, 4200- 319

Singapore

[Recruiting]
ask Contact, Singapore, 168751

[Not yet recruiting]
Singapore, Singapore, 119074

[Not yet recruiting]
Singapore, Singapore, 159964

[Not yet recruiting]
Singapore, Singapore, 308433

Slovakia

[Recruiting]
Banska Bystrica, Slovakia, 97517

[Recruiting]
Bratislava, Slovakia, 813 69

[Terminated]
Martin, Slovakia, 036 59

[Terminated]
Zilina, Slovakia, 012 07

Spain, Asturias

[Recruiting]
Oviedo, Asturias, Spain, 33012

[Terminated]
Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Recruiting]
Santiago de Compostela, La Coruna, Spain, 15705

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15706

Spain, Madrid

[Terminated]
Aravaca, Madrid, Spain, 28023

Spain

[Recruiting]
Alicante, Spain, 03016

[Recruiting]
Barcelona, Spain, 08017

[Not yet recruiting]
Barcelona, Spain, 08022

[Not yet recruiting]
Barcelona, Spain, 08035

[Terminated]
Barcelona, Spain, 08035

[Not yet recruiting]
Barcelona, Spain, 08036

[Terminated]
Bilbao, Spain, 48006

[Recruiting]
Madrid, Spain, 28002

[Terminated]
Madrid, Spain, 28040

[Not yet recruiting]
Madrid, Spain, 28046

[Not yet recruiting]
Malaga, Spain, 29010

[Terminated]
Malaga, Spain, 29010

[Terminated]
Málaga, Spain, 29010

[Not yet recruiting]
Pamplona, Spain, 31008

[Recruiting]
Sevilla, Spain, 41013

[Not yet recruiting]
Sevilla, Spain, 41071

[Not yet recruiting]
Valencia, Spain, 46014

[Not yet recruiting]
Valencia, Spain, 46015

[Terminated]
Valencia, Spain, 46015

[Recruiting]
Valladolid, Spain, 47005

[Terminated]
Valladolid, Spain, 47005

Sweden

[Terminated]
Jönköping, Sweden, 551 85

[Recruiting]
Linköping, Sweden, 58185

[Terminated]
Luleå, Sweden, 97180

[Recruiting]
Stockholm, Sweden, 11282

[Terminated]
Uppsala, Sweden, 75185

[Terminated]
Västerås, Sweden, 721 89

[Not yet recruiting]
Örebro, Sweden, 70185

Switzerland, Waadt

[Terminated]
Lausanne, Waadt, Switzerland, 1011

Switzerland

[Recruiting]
Basel, Switzerland, 4031

[Recruiting]
Bern, Switzerland, 3010

[Not yet recruiting]
Genève, Switzerland, 1211

[Recruiting]
Zürich, Switzerland, 8091

United Kingdom, Devon

[Recruiting]

Torbay, Devon, United Kingdom, TQ2 7AA

[Terminated]

Torbay, Devon, United Kingdom, TQ2 7AA

United Kingdom, Gloucestershire

[Not yet recruiting]

Gloucester, Gloucestershire, United Kingdom, GL1 3NN

United Kingdom, Grampian

[Recruiting]

Aberdeen, Grampian, United Kingdom, AB25 2ZN

United Kingdom, Greater London

[Recruiting]

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Recruiting]

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Merseyside

[Not yet recruiting]

Liverpool, Merseyside, United Kingdom, L7 8XP

United Kingdom, Northern Ireland

[Recruiting]

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]

Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Recruiting]

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Recruiting]
Birmingham, United Kingdom, B4 7ET

[Terminated]
Bristol, United Kingdom, BS1 2LX

[Not yet recruiting]
Dorchester, United Kingdom, DT1 2JY

[Not yet recruiting]
London, United Kingdom, EC1V 2PD

[Recruiting]
London, United Kingdom, NW1 5QH

[Terminated]
Manchester, United Kingdom, M13 9PT

[Not yet recruiting]
Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]
Oxford, United Kingdom, OX3 9DU

[Recruiting]
Plymouth, United Kingdom, PL6 8BX

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

Regeneron Ex. 2001
Fresenius v. Regeneron
IPR2025-01269
Page 2332 of 3000

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	◉	◉	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: April 2, 2009 (v12)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification: April 2009

Overall Status: Recruiting

Study Start: April 2008

Primary Completion: July 2011 [Anticipated]

Study Completion: July 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: April 2, 2009

Last Update Posted: April 3, 2009 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm&#xfffd;, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Buenos Aires**

[Terminated]
Olivos, Buenos Aires, Argentina, B1636CSS

Argentina, Capital Federal

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Terminated]
Buenos Aires, Capital Federal, Argentina, C1120AAN

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1122AAI

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Recruiting]
Rosario, Santa Fe, Argentina, S2000ANJ

Argentina, Tucumán

[Terminated]
San Miguel de Tucumán, Tucumán, Argentina, 4000

Argentina

[Not yet recruiting]
Buenos Aires, Argentina

[Terminated]
Córdoba, Argentina, 5000

[Recruiting]
Córdoba, Argentina, X5000IIT

[Not yet recruiting]
Mendoza, Argentina, M5500GGK

Australia, New South Wales

[Recruiting]
Chatswood, New South Wales, Australia, 2067

[Not yet recruiting]
Sydney, New South Wales, Australia, 2000

[Recruiting]
Westmead, New South Wales, Australia, 2145

Australia, South Australia

[Terminated]
Adelaide, South Australia, Australia, 5043

Australia, Victoria

[Recruiting]
East Melbourne, Victoria, Australia, 3002

[Recruiting]
Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]
Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]
Parramatta, Australia, 2150

Austria, Steiermark

[Not yet recruiting]
Graz, Steiermark, Austria, 8036

Austria, Tirol

[Recruiting]
Innsbruck, Tirol, Austria, 6020

Austria

[Not yet recruiting]
Linz, Austria, 4021

[Terminated]
Salzburg, Austria, 5020

[Recruiting]
Wien, Austria, 1090

[Terminated]
Wien, Austria, 1180

Belgium

[Not yet recruiting]
Bruxelles - Brussel, Belgium, 1020

[Terminated]
Bruxelles - Brussel, Belgium, 1070

[Terminated]
Gent, Belgium, 9000

[Terminated]
Leuven, Belgium, 3000

[Recruiting]
Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]
Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]
Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Not yet recruiting]
Araraquara, SP, Brazil, 14801-310

[Recruiting]
Sao Paulo, SP, Brazil, 04023-900

[Not yet recruiting]
São Paulo, SP, Brazil, 05651-901

Brazil

[Terminated]
Florianopolis, Brazil, 88015-080

[Not yet recruiting]
Minas Gerais, Brazil, 30150-270

Colombia

[Recruiting]
Bogota, Colombia

[Terminated]
Bogotá, Colombia

[Recruiting]
Cali, Colombia

[Terminated]
Floridablanca-Santander, Colombia

[Not yet recruiting]
Medellín, Colombia

[Terminated]
Medellín, Colombia

[Recruiting]
Medellín, Colombia

Czech Republic

[Recruiting]
Brno, Czech Republic, 62500

[Terminated]

Hradec Kralove, Czech Republic, 500 05

[Recruiting]

Olomouc, Czech Republic, 775 20

[Not yet recruiting]

Praha 10, Czech Republic, 10034

[Terminated]

Praha 2, Czech Republic, 12808

[Recruiting]

Praha 4, Czech Republic, 14000

[Not yet recruiting]

Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

[Recruiting]

Paris, Cedex 12, France, 75557

France

[Not yet recruiting]

Besancon, France, 25030

[Recruiting]

Bordeaux, France, 33000

[Recruiting]

Dijon Cedex, France, BP 1542-21

[Not yet recruiting]

Grenoble, France, 38043

[Recruiting]

Lyon, France, 69003

[Recruiting]

Lyon, France, 69006

[Recruiting]
Marseille, France, 13008

[Terminated]
Montpellier, France, 34295

[Recruiting]
Nantes Cedex, France, 44035

[Recruiting]
Paris Cedex 10, France, 75475

[Recruiting]
Paris, France, 75015

Germany, Baden-Württemberg

[Recruiting]
Freiburg, Baden-Württemberg, Germany, 79106

[Recruiting]
Heidelberg, Baden-Württemberg, Germany, 69120

[Recruiting]
Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

[Terminated]
Erlangen, Bayern, Germany, 91054

[Recruiting]
München, Bayern, Germany, 81675

[Not yet recruiting]
Regensburg, Bayern, Germany, 93053

Germany, Hessen

[Not yet recruiting]
Darmstadt, Hessen, Germany, 64276

Germany, Niedersachsen

[Not yet recruiting]
Göttingen, Niedersachsen, Germany, 37075

Germany, Nordrhein-Westfalen

[Recruiting]
Aachen, Nordrhein-Westfalen, Germany, 52074

[Recruiting]
Bonn, Nordrhein-Westfalen, Germany, 53105

[Terminated]
Duisburg, Nordrhein-Westfalen, Germany, 47119

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40219

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40225

[Not yet recruiting]
Essen, Nordrhein-Westfalen, Germany, 45147

[Recruiting]
Köln, Nordrhein-Westfalen, Germany, 50931

[Terminated]
Köln, Nordrhein-Westfalen, Germany, 50996

[Not yet recruiting]
Köln, Nordrhein-Westfalen, Germany, 51109

[Recruiting]
Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

[Not yet recruiting]
Ludwigshafen, Rheinland-Pfalz, Germany, 67063

[Recruiting]
Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

[Not yet recruiting]
Homburg, Saarland, Germany, 66421

[Terminated]
Sulzbach, Saarland, Germany, 66280

Germany, Sachsen

[Not yet recruiting]
Dresden, Sachsen, Germany, 01067

[Recruiting]
Dresden, Sachsen, Germany, 01307

[Recruiting]
Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

[Recruiting]
Kiel, Schleswig-Holstein, Germany, 24105

[Not yet recruiting]
Lübeck, Schleswig-Holstein, Germany, 23538

Germany

[Not yet recruiting]
Berlin, Germany, 12200

[Terminated]
Berlin, Germany, 13125

[Recruiting]
Hamburg, Germany, 20251

Hungary

[Recruiting]
Budapest, Hungary, 1036

[Recruiting]

Budapest, Hungary, 1089

[Recruiting]

Budapest, Hungary, 1106

[Recruiting]

Veszprem, Hungary, 8200

India, Maharashtra

[Recruiting]

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Recruiting]

Chennai, Tamil Nadu, India, 600 006

[Recruiting]

Coimbatore, Tamil Nadu, India, 641014

[Recruiting]

Madurai, Tamil Nadu, India, 625 020

[Recruiting]

Pondicherry, Tamil Nadu, India, 600007

India

[Recruiting]

Bangalore, India, 560010

[Recruiting]

Chandigarh, India, 160062

[Recruiting]

Gugarat, India

[Recruiting]

Hyderabad, India, 500 034

[Recruiting]

Kerala, India, 683572

[Recruiting]
Kolkata, India, 700073

[Recruiting]
Mumbai, India, 400 050

[Recruiting]
New Delhi, India, 110002

[Recruiting]
New Delhi, India, 110029

[Recruiting]
Orissa, India, 751 024

Israel

[Recruiting]
Afula, Israel, 18101

[Not yet recruiting]
Beer Sheva, Israel, 84101

[Not yet recruiting]
Haifa, Israel, 34362

[Recruiting]
Jerusalem, Israel, 91120

[Recruiting]
Kfar Saba, Israel, 44281

[Recruiting]
Petach Tikva, Israel, 49100

[Recruiting]
Rehovot, Israel, 76100

[Recruiting]
Tel Aviv, Israel, 64239

[Recruiting]
Tel Hashomer, Israel, 52621

[Recruiting]
Zerifin, Israel, 70300

Italy

[Not yet recruiting]
Ancona, Italy, 60020

[Not yet recruiting]
Bari, Italy, 70124

[Terminated]
Bologna, Italy, 40133

[Not yet recruiting]
Catania, Italy

[Not yet recruiting]
Firenze, Italy, 50139

[Recruiting]
Genova, Italy, 16132

[Recruiting]
Milano, Italy, 20132

[Not yet recruiting]
Milano, Italy, 20142

[Recruiting]
Milano, Italy, 20142

[Not yet recruiting]
Padova, Italy, 35128

[Recruiting]
Roma, Italy, 00133

[Not yet recruiting]

Roma, Italy, 00168

[Recruiting]
Roma, Italy, 00198

[Not yet recruiting]
Siena, Italy, 53100

[Not yet recruiting]
Torino, Italy, 10126

[Terminated]
Trieste, Italy, 34100

[Not yet recruiting]
Udine, Italy, 33100

[Not yet recruiting]
Varese, Italy, 21100

[Terminated]
Verona, Italy, 37121

Japan, Aichi

[Recruiting]
Nagoya, Aichi, Japan, 466-8560

[Recruiting]
Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Recruiting]
Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Recruiting]
Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

[Recruiting]

Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Recruiting]

Kita, Kagawa, Japan, 761-0793

Japan, Osaka

[Recruiting]

Hirakata, Osaka, Japan, 573-1191

[Recruiting]

Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Recruiting]

Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Recruiting]

Chiyoda-ku, Tokyo, Japan, 101-8309

[Recruiting]

Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

[Recruiting]

Fukuoka, Japan, 812-8582

[Recruiting]

Fukushima, Japan, 960-1295

[Recruiting]

Kagoshima, Japan, 890-8520

[Recruiting]

Kyoto, Japan, 606-8507

Korea, Republic of, Gyeonggi-do

[Not yet recruiting]
Seongnam, Gyeonggi-do, Korea, Republic of, 463 707

Korea, Republic of, Korea

[Not yet recruiting]
Seoul, Korea, Korea, Republic of, 110-744

Korea, Republic of

[Not yet recruiting]
Incheon, Korea, Republic of, 405-760

[Not yet recruiting]
Seoul, Korea, Republic of, 110 744

[Not yet recruiting]
Seoul, Korea, Republic of, 138-736

[Not yet recruiting]
Seoul, Korea, Republic of, 152-703

Latvia

[Recruiting]
Riga, Latvia, 1002

[Recruiting]
Riga, Latvia, 1009

[Terminated]
Riga, Latvia

Mexico, DF

[Recruiting]
Mexico City, DF, Mexico, 06800

[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Estado de México

[Terminated]
Metepec, Estado de México, Mexico, 52140

Mexico, Jalisco

[Recruiting]
Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64060

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64460

Mexico

[Not yet recruiting]
Chihuahua, Mexico, 31238

[Not yet recruiting]
Mexico City, Mexico, 06030

[Recruiting]
México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]
Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Recruiting]
Nijmegen, EX, Netherlands, 6525

Netherlands, Noord Brabant

[Terminated]
Eindhoven, Noord Brabant, Netherlands, 5623 EJ

Netherlands

[Not yet recruiting]
Groningen, Netherlands, 9713 GZ

[Recruiting]
Leiden, Netherlands, 2333 ZA

[Recruiting]
Rotterdam, Netherlands, 3015 GD

Poland

[Not yet recruiting]
Bydgoszcz, Poland, 85-631

[Recruiting]
Gdansk, Poland, 80-952

[Recruiting]
Katowice, Poland, 40-760

[Not yet recruiting]
Poznan, Poland, 60-355

[Terminated]
Sosnowiec, Poland, 41-200

[Not yet recruiting]
Warszawa, Poland, 00-416

[Not yet recruiting]
Warszawa, Poland, 00-621

[Terminated]
Warszawa, Poland, 01-755

[Recruiting]
Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Recruiting]
Wroclaw, Poland, 50-368

Portugal

[Recruiting]
Coimbra, Portugal, 3000-548

[Not yet recruiting]
Lisboa, Portugal, 1649-035

[Not yet recruiting]
Porto, Portugal, 4200- 319

Singapore

[Recruiting]
ask Contact, Singapore, 168751

[Not yet recruiting]
Singapore, Singapore, 119074

[Not yet recruiting]
Singapore, Singapore, 159964

[Not yet recruiting]
Singapore, Singapore, 308433

Slovakia

[Recruiting]
Banska Bystrica, Slovakia, 97517

[Recruiting]
Bratislava, Slovakia, 813 69

[Terminated]
Martin, Slovakia, 036 59

[Terminated]
Zilina, Slovakia, 012 07

Spain, Asturias

[Recruiting]
Oviedo, Asturias, Spain, 33012

[Terminated]
Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Recruiting]
Santiago de Compostela, La Coruna, Spain, 15705

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15706

Spain, Madrid

[Terminated]
Aravaca, Madrid, Spain, 28023

Spain

[Recruiting]
Alicante, Spain, 03016

[Recruiting]
Barcelona, Spain, 08017

[Not yet recruiting]
Barcelona, Spain, 08022

[Not yet recruiting]
Barcelona, Spain, 08035

[Terminated]
Barcelona, Spain, 08035

[Not yet recruiting]
Barcelona, Spain, 08036

[Terminated]
Bilbao, Spain, 48006

[Recruiting]
Madrid, Spain, 28002

[Terminated]
Madrid, Spain, 28040

[Not yet recruiting]
Madrid, Spain, 28046

[Not yet recruiting]
Malaga, Spain, 29010

[Terminated]
Malaga, Spain, 29010

[Terminated]
Málaga, Spain, 29010

[Not yet recruiting]
Pamplona, Spain, 31008

[Recruiting]
Sevilla, Spain, 41013

[Not yet recruiting]
Sevilla, Spain, 41071

[Not yet recruiting]
Valencia, Spain, 46014

[Not yet recruiting]
Valencia, Spain, 46015

[Terminated]
Valencia, Spain, 46015

[Recruiting]
Valladolid, Spain, 47005

[Terminated]
Valladolid, Spain, 47005

Sweden

[Terminated]
Jönköping, Sweden, 551 85

[Recruiting]
Linköping, Sweden, 58185

[Terminated]
Luleå, Sweden, 97180

[Recruiting]
Stockholm, Sweden, 11282

[Terminated]
Uppsala, Sweden, 75185

[Terminated]
Västerås, Sweden, 721 89

[Not yet recruiting]
Örebro, Sweden, 70185

Switzerland, Waadt

[Terminated]
Lausanne, Waadt, Switzerland, 1011

Switzerland

[Recruiting]
Basel, Switzerland, 4031

[Recruiting]
Bern, Switzerland, 3010

[Not yet recruiting]
Genève, Switzerland, 1211

[Recruiting]
Zürich, Switzerland, 8091

United Kingdom, Devon

[Recruiting]

Torbay, Devon, United Kingdom, TQ2 7AA

[Terminated]

Torbay, Devon, United Kingdom, TQ2 7AA

United Kingdom, Gloucestershire

[Not yet recruiting]

Gloucester, Gloucestershire, United Kingdom, GL1 3NN

United Kingdom, Grampian

[Recruiting]

Aberdeen, Grampian, United Kingdom, AB25 2ZN

United Kingdom, Greater London

[Recruiting]

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Recruiting]

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Merseyside

[Not yet recruiting]

Liverpool, Merseyside, United Kingdom, L7 8XP

United Kingdom, Northern Ireland

[Recruiting]

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]

Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Recruiting]

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Recruiting]
Birmingham, United Kingdom, B4 7ET

[Terminated]
Bristol, United Kingdom, BS1 2LX

[Not yet recruiting]
Dorchester, United Kingdom, DT1 2JY

[Not yet recruiting]
London, United Kingdom, EC1V 2PD

[Recruiting]
London, United Kingdom, NW1 5QH

[Terminated]
Manchester, United Kingdom, M13 9PT

[Not yet recruiting]
Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]
Oxford, United Kingdom, OX3 9DU

[Recruiting]
Plymouth, United Kingdom, PL6 8BX

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	◉	◉	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: March 5, 2009 (v11)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification: March 2009

Overall Status: Recruiting

Study Start: April 2008

Primary Completion: July 2011 [Anticipated]

Study Completion: July 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: March 5, 2009

Last Update Posted: March 6, 2009 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm², including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Buenos Aires**

[Terminated]
Olivos, Buenos Aires, Argentina, B1636CSS

Argentina, Capital Federal

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Terminated]
Buenos Aires, Capital Federal, Argentina, C1120AAN

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1122AAI

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Recruiting]
Rosario, Santa Fe, Argentina, S2000ANJ

Argentina, Tucumán

[Terminated]
San Miguel de Tucumán, Tucumán, Argentina, 4000

Argentina

[Not yet recruiting]
Buenos Aires, Argentina

[Terminated]
Córdoba, Argentina, 5000

[Recruiting]
Córdoba, Argentina, X5000IIT

[Not yet recruiting]
Mendoza, Argentina, M5500GGK

Australia, New South Wales

[Recruiting]
Chatswood, New South Wales, Australia, 2067

[Not yet recruiting]
Sydney, New South Wales, Australia, 2000

[Recruiting]
Westmead, New South Wales, Australia, 2145

Australia, South Australia

[Terminated]
Adelaide, South Australia, Australia, 5043

Australia, Victoria

[Recruiting]
East Melbourne, Victoria, Australia, 3002

[Recruiting]
Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]
Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]
Parramatta, Australia, 2150

Austria, Steiermark

[Not yet recruiting]
Graz, Steiermark, Austria, 8036

Austria, Tirol

[Recruiting]
Innsbruck, Tirol, Austria, 6020

Austria

[Not yet recruiting]
Linz, Austria, 4021

[Terminated]
Salzburg, Austria, 5020

[Recruiting]
Wien, Austria, 1090

[Terminated]
Wien, Austria, 1180

Belgium

[Not yet recruiting]
Bruxelles - Brussel, Belgium, 1020

[Terminated]
Bruxelles - Brussel, Belgium, 1070

[Terminated]
Gent, Belgium, 9000

[Terminated]
Leuven, Belgium, 3000

[Recruiting]
Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]
Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]
Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Not yet recruiting]
Araraquara, SP, Brazil, 14801-310

[Not yet recruiting]
Sao Paulo, SP, Brazil, 04023-900

[Not yet recruiting]
São Paulo, SP, Brazil, 05651-901

Brazil

[Terminated]
Florianopolis, Brazil, 88015-080

[Not yet recruiting]
Minas Gerais, Brazil, 30150-270

Colombia

[Recruiting]
Bogota, Colombia

[Terminated]
Bogotá, Colombia

[Recruiting]
Cali, Colombia

[Terminated]
Floridablanca-Santander, Colombia

[Not yet recruiting]
Medellín, Colombia

[Terminated]
Medellín, Colombia

[Recruiting]
Medellín, Colombia

Czech Republic

[Recruiting]
Brno, Czech Republic, 62500

[Terminated]

Hradec Kralove, Czech Republic, 500 05

[Not yet recruiting]

Olomouc, Czech Republic, 775 20

[Not yet recruiting]

Praha 10, Czech Republic, 10034

[Terminated]

Praha 2, Czech Republic, 12808

[Recruiting]

Praha 4, Czech Republic, 14000

[Not yet recruiting]

Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

[Recruiting]

Paris, Cedex 12, France, 75557

France

[Not yet recruiting]

Besancon, France, 25030

[Recruiting]

Bordeaux, France, 33000

[Recruiting]

Dijon Cedex, France, BP 1542-21

[Not yet recruiting]

Grenoble, France, 38043

[Recruiting]

Lyon, France, 69003

[Recruiting]

Lyon, France, 69006

[Recruiting]
Marseille, France, 13008

[Terminated]
Montpellier, France, 34295

[Recruiting]
Nantes Cedex, France, 44035

[Recruiting]
Paris Cedex 10, France, 75475

[Recruiting]
Paris, France, 75015

Germany, Baden-Württemberg

[Recruiting]
Freiburg, Baden-Württemberg, Germany, 79106

[Recruiting]
Heidelberg, Baden-Württemberg, Germany, 69112

[Recruiting]
Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

[Terminated]
Erlangen, Bayern, Germany, 91054

[Recruiting]
München, Bayern, Germany, 81675

[Not yet recruiting]
Regensburg, Bayern, Germany, 93053

Germany, Hessen

[Not yet recruiting]
Darmstadt, Hessen, Germany, 64276

Germany, Niedersachsen

[Not yet recruiting]
Göttingen, Niedersachsen, Germany, 37075

Germany, Nordrhein-Westfalen

[Recruiting]
Aachen, Nordrhein-Westfalen, Germany, 52074

[Recruiting]
Bonn, Nordrhein-Westfalen, Germany, 53105

[Terminated]
Duisburg, Nordrhein-Westfalen, Germany, 47119

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40219

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40225

[Not yet recruiting]
Essen, Nordrhein-Westfalen, Germany, 45147

[Recruiting]
Köln, Nordrhein-Westfalen, Germany, 50931

[Terminated]
Köln, Nordrhein-Westfalen, Germany, 50996

[Not yet recruiting]
Köln, Nordrhein-Westfalen, Germany, 51109

[Recruiting]
Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

[Not yet recruiting]
Ludwigshafen, Rheinland-Pfalz, Germany, 67063

[Recruiting]
Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

[Not yet recruiting]
Homburg, Saarland, Germany, 66421

[Terminated]
Sulzbach, Saarland, Germany, 66280

Germany, Sachsen

[Not yet recruiting]
Dresden, Sachsen, Germany, 01067

[Recruiting]
Dresden, Sachsen, Germany, 01307

[Recruiting]
Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

[Recruiting]
Kiel, Schleswig-Holstein, Germany, 24105

[Not yet recruiting]
Lübeck, Schleswig-Holstein, Germany, 23538

Germany

[Not yet recruiting]
Berlin, Germany, 12200

[Terminated]
Berlin, Germany, 13125

[Recruiting]
Hamburg, Germany, 20251

Hungary

[Recruiting]
Budapest, Hungary, 1036

[Recruiting]

Budapest, Hungary, 1089

[Recruiting]

Budapest, Hungary, 1106

[Recruiting]

Veszprem, Hungary, 8200

India, Maharashtra

[Recruiting]

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Recruiting]

Chennai, Tamil Nadu, India, 600 006

[Recruiting]

Coimbatore, Tamil Nadu, India, 641014

[Recruiting]

Madurai, Tamil Nadu, India, 625 020

[Recruiting]

Pondicherry, Tamil Nadu, India, 600007

India

[Recruiting]

Bangalore, India, 560010

[Recruiting]

Chandigarh, India, 160062

[Recruiting]

Gugarat, India

[Recruiting]

Hyderabad, India, 500 034

[Recruiting]

Kerala, India, 683572

[Recruiting]
Kolkata, India, 700073

[Recruiting]
Mumbai, India, 400 050

[Recruiting]
New Delhi, India, 110002

[Recruiting]
New Delhi, India, 110029

[Recruiting]
Orissa, India, 751 024

Israel

[Recruiting]
Afula, Israel, 18101

[Not yet recruiting]
Beer Sheva, Israel, 84101

[Not yet recruiting]
Haifa, Israel, 34362

[Recruiting]
Jerusalem, Israel, 91120

[Recruiting]
Kfar Saba, Israel, 44281

[Recruiting]
Petach Tikva, Israel, 49100

[Recruiting]
Rehovot, Israel, 76100

[Recruiting]
Tel Aviv, Israel, 64239

[Recruiting]
Tel Hashomer, Israel, 52621

[Recruiting]
Zerifin, Israel, 70300

Italy

[Not yet recruiting]
Ancona, Italy, 60020

[Not yet recruiting]
Bari, Italy, 70124

[Terminated]
Bologna, Italy, 40133

[Not yet recruiting]
Catania, Italy

[Not yet recruiting]
Firenze, Italy, 50139

[Recruiting]
Genova, Italy, 16132

[Not yet recruiting]
Milano, Italy, 20132

[Not yet recruiting]
Milano, Italy, 20142

[Recruiting]
Milano, Italy, 20142

[Not yet recruiting]
Padova, Italy, 35128

[Recruiting]
Roma, Italy, 00133

[Not yet recruiting]

Roma, Italy, 00168

[Recruiting]
Roma, Italy, 00198

[Not yet recruiting]
Siena, Italy, 53100

[Not yet recruiting]
Torino, Italy, 10126

[Terminated]
Trieste, Italy, 34100

[Not yet recruiting]
Udine, Italy, 33100

[Not yet recruiting]
Varese, Italy, 21100

[Terminated]
Verona, Italy, 37121

Japan, Aichi

[Recruiting]
Nagoya, Aichi, Japan, 466-8560

[Recruiting]
Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Recruiting]
Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Recruiting]
Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

[Not yet recruiting]
Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Recruiting]
Kita, Kagawa, Japan, 761-0793

Japan, Osaka

[Recruiting]
Hirakata, Osaka, Japan, 573-1191

[Recruiting]
Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Recruiting]
Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Recruiting]
Chiyoda-ku, Tokyo, Japan, 101-8309

[Recruiting]
Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

[Recruiting]
Fukuoka, Japan, 812-8582

[Recruiting]
Fukushima, Japan, 960-1295

[Recruiting]
Kagoshima, Japan, 890-8520

[Recruiting]
Kyoto, Japan, 606-8507

Korea, Republic of, Korea

[Not yet recruiting]
Seoul, Korea, Korea, Republic of, 110-744

Korea, Republic of

[Not yet recruiting]
Incheon, Korea, Republic of, 405-760

[Not yet recruiting]
Kungki-do, Korea, Republic of, 463 707

[Not yet recruiting]
Seoul, Korea, Republic of, 110 744

[Not yet recruiting]
Seoul, Korea, Republic of, 138-736

[Not yet recruiting]
Seoul, Korea, Republic of, 152-703

Latvia

[Recruiting]
Riga, Latvia, 1002

[Recruiting]
Riga, Latvia, 1009

[Terminated]
Riga, Latvia

Mexico, DF

[Recruiting]
Mexico City, DF, Mexico, 06800

[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Estado de México

[Terminated]

Metepec, Estado de México, Mexico, 52140

Mexico, Jalisco

[Recruiting]

Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Recruiting]

Monterrey, Nuevo Leon, Mexico, 64060

[Recruiting]

Monterrey, Nuevo Leon, Mexico, 64460

Mexico

[Not yet recruiting]

Chihuahua, Mexico, 31238

[Not yet recruiting]

Mexico City, Mexico, 06030

[Recruiting]

México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]

Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Recruiting]

Nijmegen, EX, Netherlands, 6525

Netherlands, Noord Brabant

[Terminated]

Eindhoven, Noord Brabant, Netherlands, 5623 EJ

Netherlands

[Not yet recruiting]
Groningen, Netherlands, 9713 GZ

[Recruiting]
Leiden, Netherlands, 2333 ZA

[Recruiting]
Rotterdam, Netherlands, 3015 GD

Poland

[Not yet recruiting]
Bydgoszcz, Poland, 85-631

[Not yet recruiting]
Gdansk, Poland, 80-952

[Recruiting]
Katowice, Poland, 40-760

[Not yet recruiting]
Poznan, Poland, 60-355

[Terminated]
Sosnowiec, Poland, 41-200

[Not yet recruiting]
Warszawa, Poland, 00-416

[Not yet recruiting]
Warszawa, Poland, 00-621

[Terminated]
Warszawa, Poland, 01-755

[Recruiting]
Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Recruiting]

Wroclaw, Poland, 50-368

Portugal

[Recruiting]
Coimbra, Portugal, 3000-548

[Not yet recruiting]
Lisboa, Portugal, 1649-035

[Not yet recruiting]
Porto, Portugal, 4200- 319

Singapore

[Recruiting]
ask Contact, Singapore, 168751

[Not yet recruiting]
Singapore, Singapore, 119074

[Not yet recruiting]
Singapore, Singapore, 159964

[Not yet recruiting]
Singapore, Singapore, 308433

Slovakia

[Recruiting]
Banska Bystrica, Slovakia, 97517

[Not yet recruiting]
Bratislava, Slovakia, 813 69

[Terminated]
Martin, Slovakia, 036 59

[Terminated]
Zilina, Slovakia, 012 07

Spain, Asturias

[Not yet recruiting]
Oviedo, Asturias, Spain, 33012

[Terminated]
Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Recruiting]
Santiago de Compostela, La Coruna, Spain, 15705

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15706

Spain, Madrid

[Terminated]
Aravaca, Madrid, Spain, 28023

Spain

[Recruiting]
Alicante, Spain, 03016

[Recruiting]
Barcelona, Spain, 08017

[Not yet recruiting]
Barcelona, Spain, 08022

[Not yet recruiting]
Barcelona, Spain, 08035

[Terminated]
Barcelona, Spain, 08035

[Not yet recruiting]
Barcelona, Spain, 08036

[Terminated]
Bilbao, Spain, 48006

[Not yet recruiting]

Madrid, Spain, 28002

[Terminated]
Madrid, Spain, 28040

[Not yet recruiting]
Madrid, Spain, 28046

[Not yet recruiting]
Malaga, Spain, 29010

[Terminated]
Malaga, Spain, 29010

[Terminated]
Málaga, Spain, 29010

[Not yet recruiting]
Pamplona, Spain, 31008

[Recruiting]
Sevilla, Spain, 41013

[Not yet recruiting]
Sevilla, Spain, 41071

[Not yet recruiting]
Valencia, Spain, 46014

[Not yet recruiting]
Valencia, Spain, 46015

[Terminated]
Valencia, Spain, 46015

[Recruiting]
Valladolid, Spain, 47005

[Terminated]
Valladolid, Spain, 47005

Sweden

[Terminated]
Jönköping, Sweden, 551 85

[Not yet recruiting]
Linköping, Sweden, 58185

[Terminated]
Luleå, Sweden, 97180

[Not yet recruiting]
Stockholm, Sweden, 11282

[Terminated]
Uppsala, Sweden, 75185

[Terminated]
Västerås, Sweden, 721 89

[Not yet recruiting]
Örebro, Sweden, 70185

Switzerland, Waadt

[Terminated]
Lausanne, Waadt, Switzerland, 1011

Switzerland

[Recruiting]
Basel, Switzerland, 4031

[Not yet recruiting]
Bern, Switzerland, 3010

[Not yet recruiting]
Genève, Switzerland, 1211

[Recruiting]
Zürich, Switzerland, 8091

United Kingdom, Devon

[Recruiting]

Torbay, Devon, United Kingdom, TQ2 7AA

[Terminated]
Torbay, Devon, United Kingdom, TQ2 7AA

United Kingdom, Gloucestershire

[Not yet recruiting]
Gloucester, Gloucestershire, United Kingdom, GL1 3NN

United Kingdom, Grampian

[Recruiting]
Aberdeen, Grampian, United Kingdom, AB25 2ZN

United Kingdom, Greater London

[Recruiting]
London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Recruiting]
Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Merseyside

[Not yet recruiting]
Liverpool, Merseyside, United Kingdom, L7 8XP

United Kingdom, Northern Ireland

[Recruiting]
Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]
Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Recruiting]
Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Recruiting]
Birmingham, United Kingdom, B4 7ET

[Terminated]
Bristol, United Kingdom, BS1 2LX

[Not yet recruiting]
Dorchester, United Kingdom, DT1 2JY

[Not yet recruiting]
London, United Kingdom, EC1V 2PD

[Recruiting]
London, United Kingdom, NW1 5QH

[Terminated]
Manchester, United Kingdom, M13 9PT

[Not yet recruiting]
Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]
Oxford, United Kingdom, OX3 9DU

[Recruiting]
Plymouth, United Kingdom, PL6 8BX

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls Scroll to the Study top

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	◉	◉	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: February 5, 2009 (v10)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification: February 2009

Overall Status: Recruiting

Study Start: April 2008

Primary Completion: July 2011 [Anticipated]

Study Completion: July 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: February 5, 2009

Last Update Posted: February 6, 2009 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women ≥ 50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm², including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Buenos Aires**

[Terminated]
Olivos, Buenos Aires, Argentina, B1636CSS

Argentina, Capital Federal

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Terminated]
Buenos Aires, Capital Federal, Argentina, C1120AAN

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1122AAI

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Recruiting]
Rosario, Santa Fe, Argentina, S2000ANJ

Argentina, Tucumán

[Terminated]
San Miguel de Tucumán, Tucumán, Argentina, 4000

Argentina

[Not yet recruiting]
Buenos Aires, Argentina

[Terminated]
Córdoba, Argentina, 5000

[Recruiting]
Córdoba, Argentina, X5000IIT

[Not yet recruiting]
Mendoza, Argentina, M5500GGK

Australia, New South Wales

[Not yet recruiting]
Chatswood, New South Wales, Australia, 2067

[Terminated]
Sydney, New South Wales, Australia, 2000

[Recruiting]
Westmead, New South Wales, Australia, 2145

Australia, South Australia

[Terminated]
Bedford Park, South Australia, Australia, 5043

Australia, Victoria

[Recruiting]
East Melbourne, Victoria, Australia, 3002

[Recruiting]
Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]
Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]
Parramatta, Australia, 2150

Austria, Steiermark

[Not yet recruiting]
Graz, Steiermark, Austria, 8036

Austria, Tirol

[Recruiting]
Innsbruck, Tirol, Austria, 6020

Austria

[Not yet recruiting]
Linz, Austria, 4021

[Terminated]
Salzburg, Austria, 5020

[Recruiting]
Wien, Austria, 1090

[Terminated]
Wien, Austria, 1180

Belgium

[Not yet recruiting]
Bruxelles - Brussel, Belgium, 1020

[Not yet recruiting]
Bruxelles - Brussel, Belgium, 1070

[Terminated]
Gent, Belgium, 9000

[Terminated]
Leuven, Belgium, 3000

[Recruiting]
Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]
Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]
Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Not yet recruiting]
Araraquara, SP, Brazil, 14801-310

[Not yet recruiting]
Sao Paulo, SP, Brazil, 04023-900

[Not yet recruiting]
Sao Pulo, SP, Brazil, 05651-901

Brazil

[Terminated]
Florianopolis, Brazil, 88015-080

[Not yet recruiting]
Minas Gerais, Brazil, 30150-270

Colombia

[Recruiting]
Bogota, Colombia

[Terminated]
Bogotá, Colombia

[Recruiting]
Cali, Colombia

[Terminated]
Floridablanca-Santander, Colombia

[Not yet recruiting]
Medellín, Colombia

[Terminated]
Medellín, Colombia

[Recruiting]
Medellín, Colombia

Czech Republic

[Recruiting]
Brno, Czech Republic, 62500

[Terminated]

Hradec Kralove, Czech Republic, 500 05

[Not yet recruiting]

Olomouc, Czech Republic, 775 20

[Not yet recruiting]

Praha 10, Czech Republic, 10034

[Terminated]

Praha 2, Czech Republic, 12808

[Recruiting]

Praha 4, Czech Republic, 14000

[Not yet recruiting]

Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

[Recruiting]

Paris, Cedex 12, France, 75557

France

[Not yet recruiting]

Besancon, France, 25030

[Recruiting]

Bordeaux, France, 33000

[Recruiting]

Dijon Cedex, France, BP 1542-21

[Not yet recruiting]

Grenoble, France, 38043

[Recruiting]

Lyon, France, 69003

[Not yet recruiting]

Lyon, France, 69006

[Recruiting]
Marseille, France, 13008

[Terminated]
Montpellier, France, 34295

[Recruiting]
Nantes Cedex, France, 44035

[Recruiting]
Paris Cedex 10, France, 75475

[Recruiting]
Paris, France, 75015

Germany, Baden-Württemberg

[Recruiting]
Freiburg, Baden-Württemberg, Germany, 79106

[Recruiting]
Heidelberg, Baden-Württemberg, Germany, 69112

[Recruiting]
Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

[Terminated]
Erlangen, Bayern, Germany, 91054

[Recruiting]
München, Bayern, Germany, 81675

[Not yet recruiting]
Regensburg, Bayern, Germany, 93053

Germany, Hessen

[Not yet recruiting]
Darmstadt, Hessen, Germany, 64276

Germany, Niedersachsen

[Not yet recruiting]
Göttingen, Niedersachsen, Germany, 37075

Germany, Nordrhein-Westfalen

[Not yet recruiting]
Aachen, Nordrhein-Westfalen, Germany, 52074

[Recruiting]
Bonn, Nordrhein-Westfalen, Germany, 53105

[Terminated]
Duisburg, Nordrhein-Westfalen, Germany, 47119

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40219

[Not yet recruiting]
Essen, Nordrhein-Westfalen, Germany, 45147

[Recruiting]
Köln, Nordrhein-Westfalen, Germany, 50931

[Terminated]
Köln, Nordrhein-Westfalen, Germany, 50996

[Not yet recruiting]
Köln, Nordrhein-Westfalen, Germany, 51109

[Recruiting]
Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

[Not yet recruiting]
Ludwigshafen, Rheinland-Pfalz, Germany, 67063

[Recruiting]
Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

[Not yet recruiting]
Homburg, Saarland, Germany, 66421

[Terminated]
Sulzbach, Saarland, Germany, 66280

Germany, Sachsen

[Not yet recruiting]
Dresden, Sachsen, Germany, 01067

[Not yet recruiting]
Dresden, Sachsen, Germany, 01307

[Recruiting]
Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

[Recruiting]
Kiel, Schleswig-Holstein, Germany, 24105

[Not yet recruiting]
Lübeck, Schleswig-Holstein, Germany, 23538

Germany

[Not yet recruiting]
Berlin, Germany, 12200

[Terminated]
Berlin, Germany, 13125

[Recruiting]
Hamburg, Germany, 20251

Hungary

[Recruiting]
Budapest, Hungary, 1036

[Recruiting]
Budapest, Hungary, 1089

[Recruiting]

Budapest, Hungary, 1106

[Recruiting]

Veszprem, Hungary, 8200

India, Maharashtra

[Recruiting]

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Recruiting]

Chennai, Tamil Nadu, India, 600 006

[Recruiting]

Coimbatore, Tamil Nadu, India, 641014

[Recruiting]

Madurai, Tamil Nadu, India, 625 020

[Recruiting]

Pondicherry, Tamil Nadu, India, 600007

India

[Recruiting]

Bangalore, India, 560010

[Recruiting]

Chandigarh, India, 160062

[Recruiting]

Gugarat, India

[Recruiting]

Hyderabad, India, 500 034

[Recruiting]

Kerala, India, 683572

[Recruiting]
Kolkata, India, 700073

[Recruiting]
Mumbai, India, 400 050

[Not yet recruiting]
New Delhi, India, 110002

[Recruiting]
New Delhi, India, 110029

[Recruiting]
Orissa, India, 751 024

Israel

[Recruiting]
Afula, Israel, 18101

[Not yet recruiting]
Beer Sheva, Israel, 84101

[Not yet recruiting]
Haifa, Israel, 34362

[Recruiting]
Jerusalem, Israel, 91120

[Not yet recruiting]
Kfar Saba, Israel, 44281

[Recruiting]
Petach Tikva, Israel, 49100

[Recruiting]
Rehovot, Israel, 76100

[Recruiting]
Tel Aviv, Israel, 64239

[Recruiting]

Tel Hashomer, Israel, 52621

[Recruiting]
Zerifin, Israel, 70300

Italy

[Not yet recruiting]
Ancona, Italy, 60020

[Not yet recruiting]
Bari, Italy, 70124

[Terminated]
Bologna, Italy, 40133

[Not yet recruiting]
Catania, Italy

[Not yet recruiting]
Firenze, Italy, 50139

[Recruiting]
Genova, Italy, 16132

[Not yet recruiting]
Milano, Italy, 20132

[Not yet recruiting]
Milano, Italy, 20142

[Recruiting]
Milano, Italy, 20142

[Not yet recruiting]
Padova, Italy, 35128

[Recruiting]
Roma, Italy, 00133

[Not yet recruiting]
Roma, Italy, 00168

[Recruiting]
Roma, Italy, 00198

[Not yet recruiting]
Siena, Italy, 53100

[Not yet recruiting]
Torino, Italy, 10126

[Not yet recruiting]
Trieste, Italy, 34100

[Not yet recruiting]
Udine, Italy, 33100

[Not yet recruiting]
Varese, Italy, 21100

[Terminated]
Verona, Italy, 37121

Japan, Aichi

[Recruiting]
Nagoya, Aichi, Japan, 466-8560

[Recruiting]
Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Recruiting]
Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Recruiting]
Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

[Not yet recruiting]
Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Not yet recruiting]
Kita, Kagawa, Japan, 761-0793

Japan, Osaka

[Recruiting]
Hirakata, Osaka, Japan, 573-1191

[Recruiting]
Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Recruiting]
Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Recruiting]
Chiyoda-ku, Tokyo, Japan, 101-8309

[Recruiting]
Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

[Recruiting]
Fukuoka, Japan, 812-8582

[Recruiting]
Fukushima, Japan, 960-1295

[Not yet recruiting]
Kagoshima, Japan, 890-8520

[Recruiting]
Kyoto, Japan, 606-8507

Korea, Republic of, Korea

[Not yet recruiting]

Seoul, Korea, Korea, Republic of, 110-744

Korea, Republic of

[Not yet recruiting]
Incheon, Korea, Republic of, 405-760

[Not yet recruiting]
Kungki-do, Korea, Republic of, 463 707

[Not yet recruiting]
Seoul, Korea, Republic of, 110 744

[Not yet recruiting]
Seoul, Korea, Republic of, 138-736

[Not yet recruiting]
Seoul, Korea, Republic of, 152-703

Latvia

[Recruiting]
Riga, Latvia, 1002

[Recruiting]
Riga, Latvia, 1009

[Not yet recruiting]
Riga, Latvia

Mexico, DF

[Recruiting]
Mexico City, DF, Mexico, 06800

[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Estado de México

[Not yet recruiting]
Metepec, Estado de México, Mexico, 52140

Mexico, Jalisco

[Recruiting]
Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64060

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64460

Mexico

[Not yet recruiting]
Chihuahua, Mexico, 31238

[Not yet recruiting]
Mexico City, Mexico, 06030

[Recruiting]
México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]
Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Recruiting]
Nijmegen, EX, Netherlands, 6525

Netherlands, Noord Brabant

[Terminated]
Eindhoven, Noord Brabant, Netherlands, 5623 EJ

Netherlands

[Not yet recruiting]
Groningen, Netherlands, 9713 GZ

[Not yet recruiting]
Leiden, Netherlands, 2333 ZA

[Not yet recruiting]
Rotterdam, Netherlands, 3015 GD

Poland

[Not yet recruiting]
Gdansk, Poland, 80-952

[Recruiting]
Katowice, Poland, 40-760

[Not yet recruiting]
Poznan, Poland, 60-355

[Terminated]
Sosnowiec, Poland, 41-200

[Not yet recruiting]
Warszawa, Poland, 00-416

[Not yet recruiting]
Warszawa, Poland, 00-621

[Terminated]
Warszawa, Poland, 01-755

[Recruiting]
Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Recruiting]
Wroclaw, Poland, 50-368

Portugal

[Recruiting]
Coimbra, Portugal, 3000-548

[Not yet recruiting]
Lisboa, Portugal, 1649-035

[Not yet recruiting]
Porto, Portugal, 4200- 319

Singapore

[Recruiting]
ask Contact, Singapore, 168751

[Not yet recruiting]
Singapore, Singapore, 119074

[Not yet recruiting]
Singapore, Singapore, 159964

[Not yet recruiting]
Singapore, Singapore, 308433

Slovakia

[Recruiting]
Banska Bystrica, Slovakia, 97517

[Not yet recruiting]
Bratislava, Slovakia, 813 69

[Terminated]
Martin, Slovakia, 036 59

[Not yet recruiting]
Zilina, Slovakia, 012 07

Spain, Asturias

[Not yet recruiting]
Oviedo, Asturias, Spain, 33012

[Terminated]
Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Recruiting]
Santiago de Compostela, La Coruna, Spain, 15705

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15706

Spain, Madrid

[Terminated]
Aravaca, Madrid, Spain, 28023

Spain

[Recruiting]
Alicante, Spain, 03016

[Not yet recruiting]
Barcelona, Spain, 08017

[Not yet recruiting]
Barcelona, Spain, 08022

[Not yet recruiting]
Barcelona, Spain, 08035

[Terminated]
Barcelona, Spain, 08035

[Not yet recruiting]
Barcelona, Spain, 08036

[Terminated]
Bilbao, Spain, 48006

[Not yet recruiting]
Madrid, Spain, 28002

[Not yet recruiting]
Madrid, Spain, 28040

[Not yet recruiting]
Madrid, Spain, 28046

[Not yet recruiting]
Malaga, Spain, 29010

[Terminated]
Malaga, Spain, 29010

[Terminated]
Málaga, Spain, 29010

[Not yet recruiting]
Pamplona, Spain, 31008

[Recruiting]
Sevilla, Spain, 41013

[Not yet recruiting]
Sevilla, Spain, 41071

[Not yet recruiting]
Valencia, Spain, 46014

[Not yet recruiting]
Valencia, Spain, 46015

[Terminated]
Valencia, Spain, 46015

[Not yet recruiting]
Valladolid, Spain, 47005

[Terminated]
Valladolid, Spain, 47005

Sweden

[Not yet recruiting]
Jönköping, Sweden, 551 85

[Not yet recruiting]
Linköping, Sweden, 58185

[Not yet recruiting]

Luleå, Sweden, 97180

[Not yet recruiting]
Stockholm, Sweden, 11282

[Terminated]
Uppsala, Sweden, 75185

[Terminated]
Västerås, Sweden, 721 89

[Not yet recruiting]
Örebro, Sweden, 70185

Switzerland, Waadt

[Terminated]
Lausanne, Waadt, Switzerland, 1011

Switzerland

[Recruiting]
Basel, Switzerland, 4031

[Not yet recruiting]
Bern, Switzerland, 3010

[Not yet recruiting]
Genève, Switzerland, 1211

[Recruiting]
Zürich, Switzerland, 8091

United Kingdom, Devon

[Recruiting]
Torbay, Devon, United Kingdom, TQ2 7AA

[Terminated]
Torbay, Devon, United Kingdom, TQ2 7AA

United Kingdom, Gloucestershire

[Not yet recruiting]

Gloucester, Gloucestershire, United Kingdom, GL1 3NN

United Kingdom, Grampian

[Recruiting]

Aberdeen, Grampian, United Kingdom, AB25 2ZN

United Kingdom, Greater London

[Recruiting]

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Recruiting]

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Merseyside

[Not yet recruiting]

Liverpool, Merseyside, United Kingdom, L7 8XP

United Kingdom, Northern Ireland

[Recruiting]

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]

Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Not yet recruiting]

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Not yet recruiting]

Birmingham, United Kingdom, B4 7ET

[Terminated]

Bristol, United Kingdom, BS1 2LX

[Not yet recruiting]
Dorchester, United Kingdom, DT1 2JY

[Not yet recruiting]
London, United Kingdom, EC1V 2PD

[Recruiting]
London, United Kingdom, NW1 5QH

[Terminated]
Manchester, United Kingdom, M13 9PT

[Not yet recruiting]
Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]
Oxford, United Kingdom, OX3 9DU

[Not yet recruiting]
Plymouth, United Kingdom, PL6 8BX

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	◉	◉	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: January 5, 2009 (v9)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

	Related Macular Degeneration (AMD) (VIEW 2)
Official Title:	A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).
Secondary IDs:	EurdaCT No.: 2007-000583-25

Study Status

Record Verification:	January 2009
Overall Status:	Recruiting
Study Start:	April 2008
Primary Completion:	July 2011 [Anticipated]
Study Completion:	July 2011 [Anticipated]
First Submitted:	March 12, 2008
First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	January 5, 2009
Last Update Posted:	January 6, 2009 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women ≥ 50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm², including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1122AAI

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Recruiting]
Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

[Not yet recruiting]
Buenos Aires, Argentina

[Not yet recruiting]
Córdoba, Argentina, X5000IIT

[Not yet recruiting]
Mendoza, Argentina, M5500GGK

Australia, New South Wales

[Not yet recruiting]
Chatswood, New South Wales, Australia, 2067

[Recruiting]
Westmead, New South Wales, Australia, 2145

Australia, Victoria

[Recruiting]
East Melbourne, Victoria, Australia, 3002

[Recruiting]
Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]
Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]
Parramatta, Australia, 2150

Austria, Steiermark

[Not yet recruiting]
Graz, Steiermark, Austria, 8036

Austria, Tirol

[Not yet recruiting]
Innsbruck, Tirol, Austria, 6020

Austria

[Not yet recruiting]
Linz, Austria, 4021

[Recruiting]
Wien, Austria, 1090

Belgium

[Not yet recruiting]
Bruxelles - Brussel, Belgium, 1020

[Not yet recruiting]
Bruxelles - Brussel, Belgium, 1070

[Recruiting]
Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]
Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]
Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Not yet recruiting]
Araraquara, SP, Brazil, 14801-310

[Not yet recruiting]
Sao Paulo, SP, Brazil, 04023-900

[Not yet recruiting]
Sao Pulo, SP, Brazil, 05651-901

Brazil

[Not yet recruiting]
Minas Gerais, Brazil, 30150-270

Colombia

[Recruiting]
Bogota, Colombia

[Recruiting]
Cali, Colombia

[Not yet recruiting]
Medellín, Colombia

[Recruiting]
Medellín, Colombia

Czech Republic

[Recruiting]
Brno, Czech Republic, 62500

[Not yet recruiting]
Olomouc, Czech Republic, 775 20

[Not yet recruiting]
Praha 10, Czech Republic, 10034

[Recruiting]

Praha 4, Czech Republic, 14000

[Not yet recruiting]

Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

[Recruiting]

Paris, Cedex 12, France, 75557

France

[Not yet recruiting]

Besancon, France, 25030

[Recruiting]

Bordeaux, France, 33000

[Recruiting]

Dijon Cedex, France, BP 1542-21

[Not yet recruiting]

Grenoble, France, 38043

[Recruiting]

Lyon, France, 69003

[Not yet recruiting]

Lyon, France, 69006

[Recruiting]

Marseille, France, 13008

[Recruiting]

Nantes Cedex, France, 44035

[Recruiting]

Paris Cedex 10, France, 75475

[Recruiting]

Paris, France, 75015

Germany, Baden-Württemberg

[Recruiting]
Freiburg, Baden-Württemberg, Germany, 79106

[Recruiting]
Heidelberg, Baden-Württemberg, Germany, 69112

[Recruiting]
Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

[Recruiting]
München, Bayern, Germany, 81675

[Not yet recruiting]
Regensburg, Bayern, Germany, 93053

Germany, Hessen

[Not yet recruiting]
Darmstadt, Hessen, Germany, 64276

Germany, Niedersachsen

[Not yet recruiting]
Göttingen, Niedersachsen, Germany, 37075

Germany, Nordrhein-Westfalen

[Not yet recruiting]
Aachen, Nordrhein-Westfalen, Germany, 52074

[Recruiting]
Bonn, Nordrhein-Westfalen, Germany, 53105

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40219

[Not yet recruiting]
Essen, Nordrhein-Westfalen, Germany, 45147

[Recruiting]
Köln, Nordrhein-Westfalen, Germany, 50931

[Not yet recruiting]
Köln, Nordrhein-Westfalen, Germany, 51109

[Recruiting]
Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

[Not yet recruiting]
Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

[Not yet recruiting]
Homburg, Saarland, Germany, 66421

Germany, Sachsen

[Not yet recruiting]
Dresden, Sachsen, Germany, 01067

[Not yet recruiting]
Dresden, Sachsen, Germany, 01307

[Recruiting]
Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

[Recruiting]
Kiel, Schleswig-Holstein, Germany, 24105

[Not yet recruiting]
Lübeck, Schleswig-Holstein, Germany, 23538

Germany

[Not yet recruiting]
Berlin, Germany, 12200

[Recruiting]
Hamburg, Germany, 20251

Hungary

[Recruiting]
Budapest, Hungary, 1036

[Recruiting]
Budapest, Hungary, 1089

[Recruiting]
Budapest, Hungary, 1106

[Recruiting]
Veszprem, Hungary, 8200

India, Maharashtra

[Recruiting]
Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Recruiting]
Chennai, Tamil Nadu, India, 600 006

[Recruiting]
Coimbatore, Tamil Nadu, India, 641014

[Recruiting]
Madurai, Tamil Nadu, India, 625 020

[Recruiting]
Pondicherry, Tamil Nadu, India, 600007

India

[Recruiting]
Bangalore, India, 560010

[Not yet recruiting]
Chandigarh, India, 160062

[Recruiting]
Gugarat, India

[Recruiting]
Hyderabad, India, 500 034

[Recruiting]
Kerala, India, 683572

[Recruiting]
Kolkata, India, 700073

[Recruiting]
Mumbai, India, 400 050

[Not yet recruiting]
New Delhi, India, 110002

[Recruiting]
New Delhi, India, 110029

[Recruiting]
Orissa, India, 751 024

Israel

[Recruiting]
Afula, Israel, 18101

[Not yet recruiting]
Beer Sheva, Israel, 84101

[Not yet recruiting]
Haifa, Israel, 34362

[Recruiting]
Jerusalem, Israel, 91120

[Not yet recruiting]
Kfar Saba, Israel, 44281

[Recruiting]

Petach Tikva, Israel, 49100

[Recruiting]
Rehovot, Israel, 76100

[Recruiting]
Tel Aviv, Israel, 64239

[Recruiting]
Tel Hashomer, Israel, 52621

[Recruiting]
Zerifin, Israel, 70300

Italy

[Not yet recruiting]
Ancona, Italy, 60020

[Not yet recruiting]
Bari, Italy, 70124

[Not yet recruiting]
Catania, Italy

[Not yet recruiting]
Firenze, Italy, 50139

[Not yet recruiting]
Genova, Italy, 16132

[Not yet recruiting]
Milano, Italy, 20132

[Not yet recruiting]
Milano, Italy, 20142

[Recruiting]
Milano, Italy, 20142

[Not yet recruiting]
Padova, Italy, 35128

[Recruiting]
Roma, Italy, 00133

[Not yet recruiting]
Roma, Italy, 00168

[Recruiting]
Roma, Italy, 00198

[Not yet recruiting]
Siena, Italy, 53100

[Not yet recruiting]
Torino, Italy, 10126

[Not yet recruiting]
Trieste, Italy, 34100

[Not yet recruiting]
Udine, Italy, 33100

[Not yet recruiting]
Varese, Italy, 21100

Japan, Aichi

[Not yet recruiting]
Nagoya, Aichi, Japan, 466-8560

[Recruiting]
Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Recruiting]
Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Recruiting]
Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

[Not yet recruiting]
Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Not yet recruiting]
Kita, Kagawa, Japan, 761-0793

Japan, Osaka

[Not yet recruiting]
Hirakata, Osaka, Japan, 573-1191

[Recruiting]
Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Recruiting]
Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Recruiting]
Chiyoda-ku, Tokyo, Japan, 101-8309

[Not yet recruiting]
Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

[Not yet recruiting]
Fukuoka, Japan, 812-8582

[Recruiting]
Fukushima, Japan, 960-1295

[Not yet recruiting]
Kagoshima, Japan, 890-8520

[Not yet recruiting]
Kyoto, Japan, 606-8507

Korea, Republic of, Korea

[Not yet recruiting]
Seoul, Korea, Korea, Republic of, 110-744

Korea, Republic of

[Not yet recruiting]
Incheon, Korea, Republic of, 405-760

[Not yet recruiting]
Kungki-do, Korea, Republic of, 463 707

[Not yet recruiting]
Seoul, Korea, Republic of, 110 744

[Not yet recruiting]
Seoul, Korea, Republic of, 138-736

[Not yet recruiting]
Seoul, Korea, Republic of, 152-703

Latvia

[Recruiting]
Riga, Latvia, 1002

[Not yet recruiting]
Riga, Latvia, 1009

[Not yet recruiting]
Riga, Latvia

Mexico, DF

[Recruiting]
Mexico City, DF, Mexico, 06800

[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Estado de México

[Not yet recruiting]
Metepec, Estado de México, Mexico, 52140

Mexico, Jalisco

[Recruiting]
Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Not yet recruiting]
Monterrey, Nuevo Leon, Mexico, 64060

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64460

Mexico

[Not yet recruiting]
Chihuahua, Mexico, 31238

[Not yet recruiting]
Mexico City, Mexico, 06030

[Recruiting]
México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]
Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Recruiting]
Nijmegen, EX, Netherlands, 6525

Netherlands

[Not yet recruiting]
Groningen, Netherlands, 9713 GZ

[Not yet recruiting]

Leiden, Netherlands, 2333 ZA

[Not yet recruiting]
Rotterdam, Netherlands, 3015 GD

Poland

[Not yet recruiting]
Gdansk, Poland, 80-952

[Recruiting]
Katowice, Poland, 40-760

[Not yet recruiting]
Poznan, Poland, 60-355

[Not yet recruiting]
Warszawa, Poland, 00-416

[Not yet recruiting]
Warszawa, Poland, 00-621

[Not yet recruiting]
Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Recruiting]
Wroclaw, Poland, 50-368

Portugal

[Recruiting]
Coimbra, Portugal, 3000-548

[Not yet recruiting]
Lisboa, Portugal, 1649-035

[Not yet recruiting]
Porto, Portugal, 4200- 319

Singapore

[Not yet recruiting]
ask Contact, Singapore, 168751

[Not yet recruiting]
Singapore, Singapore, 119074

[Not yet recruiting]
Singapore, Singapore, 159964

[Not yet recruiting]
Singapore, Singapore, 308433

Slovakia

[Recruiting]
Banska Bystrica, Slovakia, 97517

[Not yet recruiting]
Bratislava, Slovakia, 813 69

[Not yet recruiting]
Zilina, Slovakia, 012 07

Spain, Asturias

[Not yet recruiting]
Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Recruiting]
Santiago de Compostela, La Coruna, Spain, 15705

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15706

Spain

[Not yet recruiting]
Alicante, Spain, 03016

[Not yet recruiting]

Barcelona, Spain, 08017

[Not yet recruiting]
Barcelona, Spain, 08022

[Not yet recruiting]
Barcelona, Spain, 08035

[Not yet recruiting]
Barcelona, Spain, 08036

[Not yet recruiting]
Madrid, Spain, 28002

[Not yet recruiting]
Madrid, Spain, 28040

[Not yet recruiting]
Madrid, Spain, 28046

[Not yet recruiting]
Malaga, Spain, 29010

[Not yet recruiting]
Pamplona, Spain, 31008

[Not yet recruiting]
Sevilla, Spain, 41013

[Not yet recruiting]
Sevilla, Spain, 41071

[Not yet recruiting]
Valencia, Spain, 46014

[Not yet recruiting]
Valencia, Spain, 46015

[Not yet recruiting]
Valladolid, Spain, 47005

Sweden

[Not yet recruiting]
Jönköping, Sweden, 551 85

[Not yet recruiting]
Linköping, Sweden, 58185

[Not yet recruiting]
Luleå, Sweden, 97180

[Not yet recruiting]
Stockholm, Sweden, 11282

[Not yet recruiting]
Örebro, Sweden, 70185

Switzerland

[Not yet recruiting]
Basel, Switzerland, 4031

[Not yet recruiting]
Bern, Switzerland, 3010

[Not yet recruiting]
Genève, Switzerland, 1211

[Not yet recruiting]
Zürich, Switzerland, 8091

United Kingdom, Devon

[Recruiting]
Torbay, Devon, United Kingdom, TQ2 7AA

United Kingdom, Gloucestershire

[Not yet recruiting]
Gloucester, Gloucestershire, United Kingdom, GL1 3NN

United Kingdom, Grampian

[Recruiting]
Aberdeen, Grampian, United Kingdom, AB25 2ZN

United Kingdom, Greater London

[Recruiting]

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Recruiting]

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Merseyside

[Not yet recruiting]

Liverpool, Merseyside, United Kingdom, L7 8XP

United Kingdom, Northern Ireland

[Recruiting]

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]

Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Not yet recruiting]

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Not yet recruiting]

Birmingham, United Kingdom, B4 7ET

[Not yet recruiting]

Dorchester, United Kingdom, DT1 2JY

[Not yet recruiting]

London, United Kingdom, EC1V 2PD

[Recruiting]

London, United Kingdom, NW1 5QH

[Not yet recruiting]
Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]
Oxford, United Kingdom, OX3 9DU

[Not yet recruiting]
Plymouth, United Kingdom, PL6 8BX

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	◉	◉	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: December 1, 2008 (v8)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification: December 2008

Overall Status: Recruiting

Study Start: April 2008

Primary Completion: July 2011 [Anticipated]

Study Completion: July 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: December 1, 2008

Last Update Posted: December 2, 2008 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women ≥ 50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm², including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

[Recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1122AAI

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Not yet recruiting]
Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

[Not yet recruiting]
Buenos Aires, Argentina

[Not yet recruiting]
Córdoba, Argentina, X5000IIT

[Not yet recruiting]
Mendoza, Argentina, M5500GGK

Australia, New South Wales

[Not yet recruiting]
Chatswood, New South Wales, Australia, 2067

[Recruiting]
Westmead, New South Wales, Australia, 2145

Australia, Victoria

[Recruiting]
East Melbourne, Victoria, Australia, 3002

[Recruiting]
Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]

Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]

Parramatta, Australia, 2150

Austria, Steiermark

[Not yet recruiting]

Graz, Steiermark, Austria, 8036

Austria, Tirol

[Not yet recruiting]

Innsbruck, Tirol, Austria, 6020

Austria

[Not yet recruiting]

Linz, Austria, 4021

[Recruiting]

Wien, Austria, 1090

Belgium

[Not yet recruiting]

Bruxelles - Brussel, Belgium, 1070

[Recruiting]

Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]

Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]

Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Not yet recruiting]
Araraquara, SP, Brazil, 14801-310

[Not yet recruiting]
Sao Paulo, SP, Brazil, 04023-900

[Not yet recruiting]
Sao Pulo, SP, Brazil, 05651-901

Brazil

[Not yet recruiting]
Minas Gerais, Brazil, 30150-270

Colombia

[Recruiting]
Bogota, Colombia

[Recruiting]
Cali, Colombia

[Not yet recruiting]
Medellín, Colombia

[Recruiting]
Medellín, Colombia

Czech Republic

[Recruiting]
Brno, Czech Republic, 62500

[Not yet recruiting]
Olomouc, Czech Republic, 775 20

[Not yet recruiting]
Praha 10, Czech Republic, 10034

[Recruiting]
Praha 4, Czech Republic, 14000

[Not yet recruiting]
Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

[Recruiting]
Paris, Cedex 12, France, 75557

France

[Not yet recruiting]
Besancon, France, 25030

[Not yet recruiting]
Bordeaux, France, 33000

[Recruiting]
Dijon Cedex, France, BP 1542-21

[Not yet recruiting]
Grenoble, France, 38043

[Recruiting]
Lyon, France, 69003

[Not yet recruiting]
Lyon, France, 69006

[Recruiting]
Marseille, France, 13008

[Not yet recruiting]
Nantes Cedex, France, 44035

[Recruiting]
Paris Cedex 10, France, 75475

[Not yet recruiting]
Paris, France, 75015

Germany, Baden-Württemberg

[Recruiting]
Freiburg, Baden-Württemberg, Germany, 79106

[Recruiting]
Heidelberg, Baden-Württemberg, Germany, 69112

[Recruiting]
Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

[Recruiting]
München, Bayern, Germany, 81675

[Not yet recruiting]
Regensburg, Bayern, Germany, 93053

Germany, Nordrhein-Westfalen

[Not yet recruiting]
Aachen, Nordrhein-Westfalen, Germany, 52074

[Recruiting]
Bonn, Nordrhein-Westfalen, Germany, 53105

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40219

[Not yet recruiting]
Essen, Nordrhein-Westfalen, Germany, 45147

[Recruiting]
Köln, Nordrhein-Westfalen, Germany, 50931

[Not yet recruiting]
Köln, Nordrhein-Westfalen, Germany, 51109

[Recruiting]
Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

[Not yet recruiting]

Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

[Not yet recruiting]
Homburg, Saarland, Germany, 66421

Germany, Sachsen

[Not yet recruiting]
Dresden, Sachsen, Germany, 01067

[Not yet recruiting]
Dresden, Sachsen, Germany, 01307

[Recruiting]
Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

[Recruiting]
Kiel, Schleswig-Holstein, Germany, 24105

[Not yet recruiting]
Lübeck, Schleswig-Holstein, Germany, 23538

Germany

[Not yet recruiting]
Berlin, Germany, 12200

[Recruiting]
Hamburg, Germany, 20251

Hungary

[Recruiting]
Budapest, Hungary, 1036

[Recruiting]
Budapest, Hungary, 1089

[Recruiting]

Budapest, Hungary, 1106

[Recruiting]
Veszprem, Hungary, 8200

India, Maharashtra

[Recruiting]
Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Recruiting]
Chennai, Tamil Nadu, India, 600 006

[Recruiting]
Coimbatore, Tamil Nadu, India, 641014

[Recruiting]
Madurai, Tamil Nadu, India, 625 020

[Recruiting]
Pondicherry, Tamil Nadu, India, 600007

India

[Recruiting]
Bangalore, India, 560010

[Not yet recruiting]
Chandigarh, India, 160062

[Recruiting]
Gugarat, India

[Recruiting]
Hyderabad, India, 500 034

[Recruiting]
Kerala, India, 683572

[Recruiting]
Kolkata, India, 700073

[Recruiting]
Mumbai, India, 400 050

[Not yet recruiting]
New Delhi, India, 110002

[Recruiting]
New Delhi, India, 110029

[Not yet recruiting]
Orissa, India, 751 024

Israel

[Not yet recruiting]
Afula, Israel, 18101

[Not yet recruiting]
Beer Sheva, Israel, 84101

[Recruiting]
Jerusalem, Israel, 91120

[Not yet recruiting]
Kfar Saba, Israel, 44281

[Recruiting]
Petach Tikva, Israel, 49100

[Recruiting]
Rehovot, Israel, 76100

[Recruiting]
Tel Aviv, Israel, 64239

[Not yet recruiting]
Tel Hashomer, Israel, 52621

[Recruiting]
Zerifin, Israel, 70300

Italy

[Not yet recruiting]
Ancona, Italy, 60020

[Not yet recruiting]
Bari, Italy, 70124

[Not yet recruiting]
Catania, Italy

[Not yet recruiting]
Firenze, Italy, 50139

[Not yet recruiting]
Genova, Italy, 16132

[Not yet recruiting]
Milano, Italy, 20132

[Not yet recruiting]
Milano, Italy, 20142

[Recruiting]
Milano, Italy, 20142

[Not yet recruiting]
Padova, Italy, 35128

[Recruiting]
Roma, Italy, 00133

[Not yet recruiting]
Roma, Italy, 00168

[Recruiting]
Roma, Italy, 00198

[Not yet recruiting]
Siena, Italy, 53100

[Not yet recruiting]
Torino, Italy, 10126

[Not yet recruiting]
Trieste, Italy, 34100

[Not yet recruiting]
Udine, Italy, 33100

[Not yet recruiting]
Varese, Italy, 21100

Japan, Aichi

[Not yet recruiting]
Nagoya, Aichi, Japan, 466-8560

[Recruiting]
Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Recruiting]
Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Recruiting]
Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

[Not yet recruiting]
Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Not yet recruiting]
Kita, Kagawa, Japan, 761-0793

Japan, Osaka

[Not yet recruiting]
Hirakata, Osaka, Japan, 573-1191

[Recruiting]

Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Recruiting]
Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Recruiting]
Chiyoda-ku, Tokyo, Japan, 101-8309

[Not yet recruiting]
Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

[Not yet recruiting]
Fukuoka, Japan, 812-8582

[Recruiting]
Fukushima, Japan, 960-1295

[Not yet recruiting]
Kagoshima, Japan, 890-8520

[Not yet recruiting]
Kyoto, Japan, 606-8507

Korea, Republic of, Korea

[Not yet recruiting]
Seoul, Korea, Korea, Republic of, 110-744

Korea, Republic of

[Not yet recruiting]
Incheon, Korea, Republic of, 405-760

[Not yet recruiting]
Kungki-do, Korea, Republic of, 463 707

[Not yet recruiting]

Seoul, Korea, Republic of, 110 744

[Not yet recruiting]
Seoul, Korea, Republic of, 138-736

Latvia

[Recruiting]
Riga, Latvia, 1002

[Not yet recruiting]
Riga, Latvia, 1009

[Not yet recruiting]
Riga, Latvia

Mexico, DF

[Recruiting]
Mexico City, DF, Mexico, 06800

[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Estado de México

[Not yet recruiting]
Metepec, Estado de México, Mexico, 52140

Mexico, Jalisco

[Recruiting]
Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Not yet recruiting]
Monterrey, Nuevo Leon, Mexico, 64060

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64460

Mexico

[Not yet recruiting]
Chihuahua, Mexico, 31238

[Not yet recruiting]
Mexico City, Mexico, 06030

[Recruiting]
México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]
Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Recruiting]
Nijmegen, EX, Netherlands, 6525

Netherlands

[Not yet recruiting]
Groningen, Netherlands, 9713 GZ

[Not yet recruiting]
Leiden, Netherlands, 2333 ZA

[Not yet recruiting]
Rotterdam, Netherlands, 3015 GD

Poland

[Not yet recruiting]
Gdansk, Poland, 80-952

[Recruiting]
Katowice, Poland, 40-760

[Not yet recruiting]
Poznan, Poland, 60-355

[Not yet recruiting]
Warszawa, Poland, 00-416

[Not yet recruiting]
Warszawa, Poland, 00-621

[Not yet recruiting]
Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Recruiting]
Wroclaw, Poland, 50-368

Portugal

[Recruiting]
Coimbra, Portugal, 3000-548

[Not yet recruiting]
Lisboa, Portugal, 1649-035

[Not yet recruiting]
Porto, Portugal, 4200- 319

Singapore

[Not yet recruiting]
ask Contact, Singapore, 168751

[Not yet recruiting]
Singapore, Singapore, 119074

[Not yet recruiting]
Singapore, Singapore, 159964

[Not yet recruiting]
Singapore, Singapore, 308433

Slovakia

[Recruiting]
Banska Bystrica, Slovakia, 97517

[Not yet recruiting]
Bratislava, Slovakia, 813 69

[Not yet recruiting]
Zilina, Slovakia, 012 07

Spain, Asturias

[Not yet recruiting]
Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Recruiting]
Santiago de Compostela, La Coruna, Spain, 15705

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15706

Spain

[Not yet recruiting]
Alicante, Spain, 03016

[Not yet recruiting]
Barcelona, Spain, 08017

[Not yet recruiting]
Barcelona, Spain, 08022

[Not yet recruiting]
Barcelona, Spain, 08035

[Not yet recruiting]
Barcelona, Spain, 08036

[Not yet recruiting]
Madrid, Spain, 28002

[Not yet recruiting]
Madrid, Spain, 28040

[Not yet recruiting]

Madrid, Spain, 28046

[Not yet recruiting]
Malaga, Spain, 29010

[Not yet recruiting]
Pamplona, Spain, 31008

[Not yet recruiting]
Sevilla, Spain, 41013

[Not yet recruiting]
Sevilla, Spain, 41071

[Not yet recruiting]
Valencia, Spain, 46014

[Not yet recruiting]
Valencia, Spain, 46015

[Not yet recruiting]
Valladolid, Spain, 47005

Sweden

[Not yet recruiting]
Jönköping, Sweden, 551 85

[Not yet recruiting]
Linköping, Sweden, 58185

[Not yet recruiting]
Luleå, Sweden, 97180

[Not yet recruiting]
Stockholm, Sweden, 11282

[Not yet recruiting]
Örebro, Sweden, 70185

Switzerland

[Not yet recruiting]

Basel, Switzerland, 4031

[Not yet recruiting]
Bern, Switzerland, 3010

[Not yet recruiting]
Genève, Switzerland, 1211

[Not yet recruiting]
Zürich, Switzerland, 8091

United Kingdom, Devon

[Recruiting]
Torbay, Devon, United Kingdom, TQ2 7AA

United Kingdom, Gloucestershire

[Not yet recruiting]
Gloucester, Gloucestershire, United Kingdom, GL1 3NN

United Kingdom, Grampian

[Recruiting]
Aberdeen, Grampian, United Kingdom, AB25 2ZN

United Kingdom, Greater London

[Recruiting]
London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Not yet recruiting]
Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Merseyside

[Not yet recruiting]
Liverpool, Merseyside, United Kingdom, L7 8XP

United Kingdom, Northern Ireland

[Recruiting]

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]
Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Not yet recruiting]
Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Not yet recruiting]
Birmingham, United Kingdom, B4 7ET

[Not yet recruiting]
Dorchester, United Kingdom, DT1 2JY

[Not yet recruiting]
London, United Kingdom, EC1V 2PD

[Recruiting]
London, United Kingdom, NW1 5QH

[Not yet recruiting]
Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]
Oxford, United Kingdom, OX3 9DU

[Not yet recruiting]
Plymouth, United Kingdom, PL6 8BX

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	◉	◉	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: November 4, 2008 (v7)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).

Secondary IDs: EurdaCT No.: 2007-000583-25

Study Status

Record Verification: November 2008

Overall Status: Recruiting

Study Start: April 2008

Primary Completion: September 2011 [Anticipated]

Study Completion: September 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: November 4, 2008

Last Update Posted: November 5, 2008 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators:

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women ≥ 50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm², including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1122AAI

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Not yet recruiting]
Rosario, Santa Fe, Argentina, S2000ANJ

Argentina, Tucumán

[Not yet recruiting]
San Miguel de Tucumán, Tucumán, Argentina, 4000

Argentina

[Not yet recruiting]
Buenos Aires, Argentina

[Not yet recruiting]
Córdoba, Argentina, X5000IIT

[Not yet recruiting]
Mendoza, Argentina, M5500GGK

Australia, New South Wales

[Not yet recruiting]
Chatswood, New South Wales, Australia, 2067

[Recruiting]
Westmead, New South Wales, Australia, 2145

Australia, Victoria

[Recruiting]
East Melbourne, Victoria, Australia, 3002

[Recruiting]
Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]
Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]
Parramatta, Australia, 2150

Austria, Steiermark

[Not yet recruiting]
Graz, Steiermark, Austria, 8036

Austria, Tirol

[Not yet recruiting]
Innsbruck, Tirol, Austria, 6020

Austria

[Not yet recruiting]
Linz, Austria, 4021

[Recruiting]
Wien, Austria, 1090

Belgium

[Not yet recruiting]
Bruxelles - Brussel, Belgium, 1070

[Recruiting]
Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]
Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]
Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Not yet recruiting]
Araraquara, SP, Brazil, 14801-310

[Not yet recruiting]
Sao Paulo, SP, Brazil, 04023-900

[Not yet recruiting]
Sao Pulo, SP, Brazil, 05651-901

Brazil

[Not yet recruiting]
Minas Gerais, Brazil, 30150-270

Colombia

[Recruiting]
Bogota, Colombia

[Recruiting]
Cali, Colombia

[Not yet recruiting]
Medellín, Colombia

[Recruiting]
Medellín, Colombia

Czech Republic

[Not yet recruiting]
Brno, Czech Republic, 62500

[Not yet recruiting]
Olomouc, Czech Republic, 775 20

[Not yet recruiting]
Praha 10, Czech Republic, 10034

[Recruiting]
Praha 4, Czech Republic, 14000

[Not yet recruiting]
Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

[Not yet recruiting]
Paris, Cedex 12, France, 75557

France

[Not yet recruiting]
Besancon, France, 25030

[Not yet recruiting]
Bordeaux, France, 33000

[Not yet recruiting]
Dijon Cedex, France, BP 1542-21

[Not yet recruiting]
Grenoble, France, 38043

[Not yet recruiting]
Lyon, France, 69003

[Not yet recruiting]
Lyon, France, 69006

[Not yet recruiting]
Marseille, France, 13008

[Not yet recruiting]
Nantes Cedex, France, 44035

[Not yet recruiting]
Paris Cedex 10, France, 75475

[Not yet recruiting]
Paris, France, 75015

Germany, Baden-Württemberg

[Recruiting]
Freiburg, Baden-Württemberg, Germany, 79106

[Recruiting]
Heidelberg, Baden-Württemberg, Germany, 69112

[Recruiting]
Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

[Recruiting]
München, Bayern, Germany, 81675

[Not yet recruiting]
Regensburg, Bayern, Germany, 93053

Germany, Nordrhein-Westfalen

[Not yet recruiting]
Aachen, Nordrhein-Westfalen, Germany, 52074

[Recruiting]
Bonn, Nordrhein-Westfalen, Germany, 53105

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40219

[Not yet recruiting]
Essen, Nordrhein-Westfalen, Germany, 45147

[Recruiting]
Köln, Nordrhein-Westfalen, Germany, 50931

[Not yet recruiting]
Köln, Nordrhein-Westfalen, Germany, 51109

[Not yet recruiting]

Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

[Not yet recruiting]
Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Sachsen

[Not yet recruiting]
Dresden, Sachsen, Germany, 01067

[Not yet recruiting]
Dresden, Sachsen, Germany, 01307

[Recruiting]
Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

[Recruiting]
Kiel, Schleswig-Holstein, Germany, 24105

[Not yet recruiting]
Lübeck, Schleswig-Holstein, Germany, 23538

Germany

[Not yet recruiting]
Berlin, Germany, 12200

[Recruiting]
Hamburg, Germany, 20251

Hungary

[Recruiting]
Budapest, Hungary, 1036

[Recruiting]
Budapest, Hungary, 1089

[Recruiting]

Budapest, Hungary, 1106

[Recruiting]
Veszprem, Hungary, 8200

India, Maharashtra

[Recruiting]
Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Recruiting]
Chennai, Tamil Nadu, India, 600 006

[Recruiting]
Coimbatore, Tamil Nadu, India, 641014

[Recruiting]
Madurai, Tamil Nadu, India, 625 020

[Recruiting]
Pondicherry, Tamil Nadu, India, 600007

India

[Recruiting]
Bangalore, India, 560010

[Not yet recruiting]
Chandigarh, India, 160062

[Recruiting]
Gugarat, India

[Recruiting]
Hyderabad, India, 500 034

[Recruiting]
Kerala, India, 683572

[Recruiting]
Kolkata, India, 700073

[Recruiting]
Mumbai, India, 400 050

[Not yet recruiting]
New Delhi, India, 110002

[Recruiting]
New Delhi, India, 110029

[Not yet recruiting]
Orissa, India, 751 024

Israel

[Not yet recruiting]
Afula, Israel, 18101

[Recruiting]
Jerusalem, Israel, 91120

[Not yet recruiting]
Kfar Saba, Israel, 44281

[Recruiting]
Petach Tikva, Israel, 49100

[Recruiting]
Rehovot, Israel, 76100

[Recruiting]
Tel Aviv, Israel, 64239

[Not yet recruiting]
Tel Hashomer, Israel, 52621

[Recruiting]
Zerifin, Israel, 70300

Italy

[Not yet recruiting]
Ancona, Italy, 60020

[Not yet recruiting]
Bari, Italy, 70124

[Not yet recruiting]
Catania, Italy

[Not yet recruiting]
Firenze, Italy, 50139

[Not yet recruiting]
Genova, Italy, 16132

[Not yet recruiting]
Milano, Italy, 20132

[Not yet recruiting]
Milano, Italy, 20142

[Not yet recruiting]
Padova, Italy, 35128

[Recruiting]
Roma, Italy, 00133

[Not yet recruiting]
Roma, Italy, 00168

[Not yet recruiting]
Roma, Italy, 00198

[Not yet recruiting]
Siena, Italy, 53100

[Not yet recruiting]
Torino, Italy, 10126

[Not yet recruiting]
Trieste, Italy, 34100

[Not yet recruiting]
Udine, Italy, 33100

[Not yet recruiting]
Varese, Italy, 21100

Japan, Aichi

[Not yet recruiting]
Nagoya, Aichi, Japan, 466-8560

[Recruiting]
Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Recruiting]
Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Not yet recruiting]
Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

[Not yet recruiting]
Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Not yet recruiting]
Kita, Kagawa, Japan, 761-0793

Japan, Osaka

[Not yet recruiting]
Hirakata, Osaka, Japan, 573-1191

[Recruiting]
Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Not yet recruiting]
Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Not yet recruiting]
Chiyoda-ku, Tokyo, Japan, 101-8309

[Not yet recruiting]
Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

[Not yet recruiting]
Fukuoka, Japan, 812-8582

[Recruiting]
Fukushima, Japan, 960-1295

[Not yet recruiting]
Kagoshima, Japan, 890-8520

[Not yet recruiting]
Kyoto, Japan, 606-8507

Korea, Republic of, Korea

[Not yet recruiting]
Seoul, Korea, Korea, Republic of, 110-744

Korea, Republic of

[Not yet recruiting]
Kungki-do, Korea, Republic of, 463 707

[Not yet recruiting]
Seoul, Korea, Republic of, 110 744

[Not yet recruiting]
Seoul, Korea, Republic of, 138-736

Latvia

[Recruiting]
Riga, Latvia, 1002

[Not yet recruiting]
Riga, Latvia, 1009

[Not yet recruiting]
Riga, Latvia

Mexico, DF

[Recruiting]
Mexico City, DF, Mexico, 06800

[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Estado de México

[Not yet recruiting]
Metepec, Estado de México, Mexico, 52140

Mexico, Jalisco

[Recruiting]
Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Not yet recruiting]
Monterrey, Nuevo Leon, Mexico, 64060

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64460

Mexico

[Not yet recruiting]
Chihuahua, Mexico, 31238

[Not yet recruiting]
Mexico City, Mexico, 06030

[Recruiting]
México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]
Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Recruiting]
Nijmegen, EX, Netherlands, 6525

Netherlands

[Not yet recruiting]
Groningen, Netherlands, 9713 GZ

[Not yet recruiting]
Leiden, Netherlands, 2333 ZA

[Not yet recruiting]
Rotterdam, Netherlands, 3015 GD

Poland

[Not yet recruiting]
Gdansk, Poland, 80-952

[Recruiting]
Katowice, Poland, 40-760

[Not yet recruiting]
Poznan, Poland, 60-355

[Not yet recruiting]
Warszawa, Poland, 00-416

[Not yet recruiting]
Warszawa, Poland, 00-621

[Not yet recruiting]
Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Not yet recruiting]
Wroclaw, Poland, 50-368

Portugal

[Recruiting]
Coimbra, Portugal, 3000-548

[Not yet recruiting]
Lisboa, Portugal, 1649-035

[Not yet recruiting]
Porto, Portugal, 4200- 319

Singapore

[Not yet recruiting]
ask Contact, Singapore, 168751

[Not yet recruiting]
Singapore, Singapore, 119074

[Not yet recruiting]
Singapore, Singapore, 159964

[Not yet recruiting]
Singapore, Singapore, 308433

Slovakia

[Recruiting]
Banska Bystrica, Slovakia, 97517

[Not yet recruiting]
Bratislava, Slovakia, 813 69

[Not yet recruiting]
Zilina, Slovakia, 012 07

Spain, Asturias

[Not yet recruiting]

Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Recruiting]
Santiago de Compostela, La Coruna, Spain, 15705

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15706

Spain

[Not yet recruiting]
Alicante, Spain, 03016

[Not yet recruiting]
Barcelona, Spain, 08017

[Not yet recruiting]
Barcelona, Spain, 08022

[Not yet recruiting]
Barcelona, Spain, 08035

[Not yet recruiting]
Barcelona, Spain, 08036

[Not yet recruiting]
Madrid, Spain, 28002

[Not yet recruiting]
Madrid, Spain, 28040

[Not yet recruiting]
Madrid, Spain, 28046

[Not yet recruiting]
Malaga, Spain, 29010

[Not yet recruiting]
Pamplona, Spain, 31008

[Not yet recruiting]

Sevilla, Spain, 41013

[Not yet recruiting]
Sevilla, Spain, 41071

[Not yet recruiting]
Valencia, Spain, 46014

[Not yet recruiting]
Valencia, Spain, 46015

[Not yet recruiting]
Valladolid, Spain, 47005

Sweden

[Not yet recruiting]
Jönköping, Sweden, 551 85

[Not yet recruiting]
Linköping, Sweden, 58185

[Not yet recruiting]
Luleå, Sweden, 97180

[Not yet recruiting]
Stockholm, Sweden, 11282

[Not yet recruiting]
Örebro, Sweden, 70185

Switzerland

[Not yet recruiting]
Basel, Switzerland, 4031

[Not yet recruiting]
Bern, Switzerland, 3010

[Not yet recruiting]
Genève, Switzerland, 1211

[Not yet recruiting]

Zürich, Switzerland, 8091

United Kingdom, Devon

[Recruiting]

Torbay, Devon, United Kingdom, TQ2 7AA

United Kingdom, Gloucestershire

[Not yet recruiting]

Gloucester, Gloucestershire, United Kingdom, GL1 3NN

United Kingdom, Grampian

[Recruiting]

Aberdeen, Grampian, United Kingdom, AB25 2ZN

United Kingdom, Greater London

[Not yet recruiting]

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Not yet recruiting]

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Merseyside

[Not yet recruiting]

Liverpool, Merseyside, United Kingdom, L7 8XP

United Kingdom, Northern Ireland

[Not yet recruiting]

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]

Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Not yet recruiting]

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Not yet recruiting]
Birmingham, United Kingdom, B4 7ET

[Not yet recruiting]
Dorchester, United Kingdom, DT1 2JY

[Not yet recruiting]
London, United Kingdom, EC1V 2PD

[Recruiting]
London, United Kingdom, NW1 5QH

[Not yet recruiting]
Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]
Oxford, United Kingdom, OX3 9DU

[Not yet recruiting]
Plymouth, United Kingdom, PL6 8BX

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls | Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight

Version	A	B	Submitted Date	Changes
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	◉	◉	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: October 2, 2008 (v6)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-

Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).

Secondary IDs: EurdaCT No.: 2007-000583-25
311523
VIEW 2

Study Status

Record Verification: October 2008

Overall Status: Recruiting

Study Start: April 2008

Primary Completion: September 2011 [Anticipated]

Study Completion: September 2011 [Anticipated]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria: March 17, 2008

First Posted: March 18, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: October 2, 2008

Last Update Posted: October 3, 2008 [Estimate]

Sponsor/Collaborators

Sponsor: Bayer

Responsible Party:

Collaborators: Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:

U.S. FDA-regulated Device:

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women ≥ 50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm², including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1122AAI

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Not yet recruiting]
Rosario, Santa Fe, Argentina, S2000ANJ

Argentina, Tucumán

[Not yet recruiting]
San Miguel de Tucumán, Tucumán, Argentina, 4000

Argentina

[Not yet recruiting]
Córdoba, Argentina, X5000IIT

Australia, New South Wales

[Not yet recruiting]
Chatswood, New South Wales, Australia, 2067

[Recruiting]
Westmead, New South Wales, Australia, 2145

Australia, Victoria

[Recruiting]
East Melbourne, Victoria, Australia, 3002

[Recruiting]
Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]

Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]
Parramatta, Australia, 2150

Austria, Steiermark

[Not yet recruiting]
Graz, Steiermark, Austria, 8036

Austria, Tirol

[Not yet recruiting]
Innsbruck, Tirol, Austria, 6020

Austria

[Not yet recruiting]
Linz, Austria, 4021

[Recruiting]
Wien, Austria, 1090

Belgium

[Not yet recruiting]
Bruxelles - Brussel, Belgium, 1070

[Not yet recruiting]
Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]
Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]
Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Not yet recruiting]
Araraquara, SP, Brazil, 14801-310

[Not yet recruiting]
Sao Paulo, SP, Brazil, 04023-900

[Not yet recruiting]
Sao Pulo, SP, Brazil, 05651-901

Brazil

[Not yet recruiting]
Minas Gerais, Brazil, 30150-270

Colombia

[Not yet recruiting]
Bogota, Colombia

[Recruiting]
Cali, Colombia

[Not yet recruiting]
Medellín, Colombia

[Recruiting]
Medellín, Colombia

Czech Republic

[Not yet recruiting]
Brno, Czech Republic, 62500

[Not yet recruiting]
Olomouc, Czech Republic, 775 20

[Not yet recruiting]
Praha 10, Czech Republic, 10034

[Not yet recruiting]
Praha 4, Czech Republic, 14000

France, Cedex 12

[Not yet recruiting]
Paris, Cedex 12, France, 75557

France

[Not yet recruiting]
Besancon, France, 25030

[Not yet recruiting]
Bordeaux, France, 33000

[Not yet recruiting]
Dijon Cedex, France, BP 1542-21

[Not yet recruiting]
Grenoble, France, 38043

[Not yet recruiting]
Lyon, France, 69003

[Not yet recruiting]
Lyon, France, 69006

[Not yet recruiting]
Marseille, France, 13008

[Not yet recruiting]
Nantes Cedex, France, 44035

[Not yet recruiting]
Paris Cedex 10, France, 75475

[Not yet recruiting]
Paris, France, 75015

Germany, Baden-Württemberg

[Not yet recruiting]
Heidelberg, Baden-Württemberg, Germany, 69112

[Not yet recruiting]
Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

[Recruiting]
München, Bayern, Germany, 81675

[Not yet recruiting]
Regensburg, Bayern, Germany, 93053

Germany, Nordrhein-Westfalen

[Not yet recruiting]
Aachen, Nordrhein-Westfalen, Germany, 52074

[Not yet recruiting]
Bonn, Nordrhein-Westfalen, Germany, 53105

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40219

[Not yet recruiting]
Essen, Nordrhein-Westfalen, Germany, 45147

[Recruiting]
Köln, Nordrhein-Westfalen, Germany, 50931

[Not yet recruiting]
Köln, Nordrhein-Westfalen, Germany, 51109

[Not yet recruiting]
Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

[Not yet recruiting]
Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Sachsen

[Not yet recruiting]
Dresden, Sachsen, Germany, 01067

[Not yet recruiting]
Dresden, Sachsen, Germany, 01307

[Not yet recruiting]
Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

[Not yet recruiting]
Kiel, Schleswig-Holstein, Germany, 24105

Germany

[Not yet recruiting]
Berlin, Germany, 12200

[Not yet recruiting]
Hamburg, Germany, 20251

Hungary

[Recruiting]
Budapest, Hungary, 1036

[Recruiting]
Budapest, Hungary, 1089

[Not yet recruiting]
Budapest, Hungary, 1106

[Recruiting]
Veszprem, Hungary, 8200

India, Maharashtra

[Recruiting]
Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Recruiting]
Chennai, Tamil Nadu, India, 600 006

[Recruiting]
Coimbatore, Tamil Nadu, India, 641014

[Recruiting]
Madurai, Tamil Nadu, India, 625 020

[Recruiting]
Pondicherry, Tamil Nadu, India, 600007

India

[Not yet recruiting]
Bangalore, India, 560010

[Not yet recruiting]
Chandigarh, India, 160062

[Recruiting]
Gugarat, India

[Recruiting]
Hyderabad, India, 500 034

[Recruiting]
Kerala, India, 683572

[Recruiting]
Kolkata, India, 700073

[Not yet recruiting]
Mumbai, India, 400 050

[Not yet recruiting]
New Delhi, India, 110002

[Recruiting]
New Delhi, India, 110029

[Not yet recruiting]
Orissa, India, 751 024

Israel

[Not yet recruiting]
Afula, Israel, 18101

[Recruiting]
Jerusalem, Israel, 91120

[Not yet recruiting]
Kfar Saba, Israel, 44281

[Recruiting]
Petach Tikva, Israel, 49100

[Recruiting]
Rehovot, Israel, 76100

[Recruiting]
Tel Aviv, Israel, 64239

[Not yet recruiting]
Tel Hashomer, Israel, 52621

[Recruiting]
Zerifin, Israel, 70300

Italy

[Not yet recruiting]
Ancona, Italy, 60020

[Not yet recruiting]
Bari, Italy, 70124

[Not yet recruiting]
Catania, Italy

[Not yet recruiting]
Firenze, Italy, 50139

[Not yet recruiting]
Genova, Italy, 16132

[Not yet recruiting]
Milano, Italy, 20132

[Not yet recruiting]

Milano, Italy, 20142

[Not yet recruiting]
Padova, Italy, 35128

[Not yet recruiting]
Roma, Italy, 00133

[Not yet recruiting]
Roma, Italy, 00168

[Not yet recruiting]
Roma, Italy, 00198

[Not yet recruiting]
Siena, Italy, 53100

[Not yet recruiting]
Torino, Italy, 10126

[Not yet recruiting]
Trieste, Italy, 34100

[Not yet recruiting]
Udine, Italy, 33100

[Not yet recruiting]
Varese, Italy, 21100

Japan, Aichi

[Not yet recruiting]
Nagoya, Aichi, Japan, 466-8560

[Not yet recruiting]
Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Recruiting]
Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Not yet recruiting]
Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

[Not yet recruiting]
Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Not yet recruiting]
Kita, Kagawa, Japan, 761-0793

Japan, Osaka

[Not yet recruiting]
Hirakata, Osaka, Japan, 573-1191

[Not yet recruiting]
Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Not yet recruiting]
Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Not yet recruiting]
Chiyoda-ku, Tokyo, Japan, 101-8309

[Not yet recruiting]
Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

[Not yet recruiting]
Fukuoka, Japan, 812-8582

[Recruiting]
Fukushima, Japan, 960-1295

[Not yet recruiting]

Kagoshima, Japan, 890-8520

[Not yet recruiting]
Kyoto, Japan, 606-8507

Latvia

[Not yet recruiting]
Riga, Latvia, 1002

[Not yet recruiting]
Riga, Latvia, 1009

[Not yet recruiting]
Riga, Latvia

Mexico, DF

[Not yet recruiting]
Mexico City, DF, Mexico, 06800

[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Estado de México

[Not yet recruiting]
Metepec, Estado de México, Mexico, 52140

Mexico, Jalisco

[Recruiting]
Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Not yet recruiting]
Monterrey, Nuevo Leon, Mexico, 64060

[Recruiting]
Monterrey, Nuevo Leon, Mexico, 64460

Mexico

[Not yet recruiting]
Chihuahua, Mexico, 31238

[Not yet recruiting]
Mexico City, Mexico, 06030

[Not yet recruiting]
México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]
Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Not yet recruiting]
Nijmegen, EX, Netherlands, 6525

Netherlands

[Not yet recruiting]
Groningen, Netherlands, 9713 GZ

[Not yet recruiting]
Leiden, Netherlands, 2333 ZA

[Not yet recruiting]
Rotterdam, Netherlands, 3015 GD

Poland

[Not yet recruiting]
Gdansk, Poland, 80-952

[Not yet recruiting]
Katowice, Poland, 40-760

[Not yet recruiting]
Poznan, Poland, 60-355

[Not yet recruiting]
Warszawa, Poland, 00-416

[Not yet recruiting]
Warszawa, Poland, 00-621

[Not yet recruiting]
Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Not yet recruiting]
Wroclaw, Poland, 50-368

Portugal

[Not yet recruiting]
Coimbra, Portugal, 3000-548

[Not yet recruiting]
Lisboa, Portugal, 1649-035

[Not yet recruiting]
Porto, Portugal, 4200- 319

Singapore

[Not yet recruiting]
ask Contact, Singapore, 168751

[Not yet recruiting]
Singapore, Singapore, 119074

[Not yet recruiting]
Singapore, Singapore, 159964

[Not yet recruiting]
Singapore, Singapore, 308433

Slovakia

[Recruiting]
Banska Bystrica, Slovakia, 97517

[Not yet recruiting]
Bratislava, Slovakia, 813 69

[Not yet recruiting]
Zilina, Slovakia, 012 07

Spain, Asturias

[Not yet recruiting]
Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15705

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15706

Spain

[Not yet recruiting]
Alicante, Spain, 03016

[Not yet recruiting]
Barcelona, Spain, 08017

[Not yet recruiting]
Barcelona, Spain, 08022

[Not yet recruiting]
Barcelona, Spain, 08035

[Not yet recruiting]
Barcelona, Spain, 08036

[Not yet recruiting]
Madrid, Spain, 28002

[Not yet recruiting]
Madrid, Spain, 28040

[Not yet recruiting]

Madrid, Spain, 28046

[Not yet recruiting]
Malaga, Spain, 29010

[Not yet recruiting]
Pamplona, Spain, 31008

[Not yet recruiting]
Sevilla, Spain, 41013

[Not yet recruiting]
Sevilla, Spain, 41071

[Not yet recruiting]
Valencia, Spain, 46014

[Not yet recruiting]
Valencia, Spain, 46015

[Not yet recruiting]
Valladolid, Spain, 47005

Sweden

[Not yet recruiting]
Jönköping, Sweden, 551 85

[Not yet recruiting]
Linköping, Sweden, 58185

[Not yet recruiting]
Luleå, Sweden, 97180

[Not yet recruiting]
Stockholm, Sweden, 11282

[Not yet recruiting]
Örebro, Sweden, 70185

Switzerland

[Not yet recruiting]

Basel, Switzerland, 4031

[Not yet recruiting]
Bern, Switzerland, 3010

[Not yet recruiting]
Genève, Switzerland, 1211

[Not yet recruiting]
Zürich, Switzerland, 8091

United Kingdom, Devon

[Not yet recruiting]
Torbay, Devon, United Kingdom, TQ2 7AA

United Kingdom, Grampian

[Not yet recruiting]
Aberdeen, Grampian, United Kingdom, AB25 2ZN

United Kingdom, Greater London

[Not yet recruiting]
London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Not yet recruiting]
Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Merseyside

[Not yet recruiting]
Liverpool, Merseyside, United Kingdom, L7 8XP

United Kingdom, Northern Ireland

[Not yet recruiting]
Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]

Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Not yet recruiting]
Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Not yet recruiting]
Birmingham, United Kingdom, B4 7ET

[Not yet recruiting]
Dorchester, United Kingdom, DT1 2JY

[Not yet recruiting]
London, United Kingdom, EC1V 2PD

[Recruiting]
London, United Kingdom, NW1 5QH

[Not yet recruiting]
Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]
Oxford, United Kingdom, OX3 9DU

[Not yet recruiting]
Plymouth, United Kingdom, PL6 8BX

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

Regeneron Ex. 2001
Fresenius v. Regeneron
IPR2025-01269
Page 2530 of 3000

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight
3	○	○	June 19, 2008	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	◉	◉	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status
21	○	○	October 6, 2010	Study Status

Version	A	B	Submitted Date	Changes
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: September 30, 2008 (v5)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2)

Official Title:	A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).
Secondary IDs:	EurdaCT No.: 2007-000583-25 311523 VIEW 2

Study Status

Record Verification:	September 2008
Overall Status:	Recruiting
Study Start:	April 2008
Primary Completion:	April 2008 [Anticipated]
Study Completion:	September 2011 [Anticipated]
First Submitted:	March 12, 2008
First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	September 30, 2008
Last Update Posted:	October 1, 2008 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	
Collaborators:	Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women ≥ 50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
- ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm², including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1122AAI

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Not yet recruiting]
Rosario, Santa Fe, Argentina, S2000ANJ

Argentina, Tucumán

[Not yet recruiting]
San Miguel de Tucumán, Tucumán, Argentina, 4000

Argentina

[Not yet recruiting]
Córdoba, Argentina, X5000IIT

Australia, New South Wales

[Not yet recruiting]
Chatswood, New South Wales, Australia, 2067

[Recruiting]
Westmead, New South Wales, Australia, 2145

Australia, Victoria

[Recruiting]
East Melbourne, Victoria, Australia, 3002

[Not yet recruiting]
Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]

Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]
Parramatta, Australia, 2150

Austria, Steiermark

[Not yet recruiting]
Graz, Steiermark, Austria, 8036

Austria, Tirol

[Not yet recruiting]
Innsbruck, Tirol, Austria, 6020

Austria

[Not yet recruiting]
Linz, Austria, 4021

[Recruiting]
Wien, Austria, 1090

Belgium

[Not yet recruiting]
Bruxelles, Belgium, 1070

[Not yet recruiting]
Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]
Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]
Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Not yet recruiting]
Araraquara, SP, Brazil, 14801-310

[Not yet recruiting]
Sao Paulo, SP, Brazil, 04023-900

Brazil

[Not yet recruiting]
Minas Gerais, Brazil, 30150-270

[Not yet recruiting]
Sao Paulo, Brazil, 05651-901

Colombia

[Not yet recruiting]
Bogota, Colombia

[Recruiting]
Cali, Colombia

[Not yet recruiting]
Medellín, Colombia

[Recruiting]
Medellín, Colombia

Czech Republic

[Not yet recruiting]
Brno, Czech Republic, 63400

[Not yet recruiting]
Hradec Kralove, Czech Republic, 500 05

[Not yet recruiting]
Olomouc, Czech Republic, 775 20

[Not yet recruiting]
Praha 4, Czech Republic, 14000

France, Cedex 12

[Not yet recruiting]
Paris, Cedex 12, France, 75557

France

[Not yet recruiting]
Besancon, France, 25030

[Not yet recruiting]
Bordeaux, France, 33000

[Not yet recruiting]
Dijon Cedex, France, BP 1542-21

[Not yet recruiting]
Grenoble, France, 38043

[Not yet recruiting]
Lyon, France, 69003

[Not yet recruiting]
Lyon, France, 69006

[Not yet recruiting]
Marseille, France, 13008

[Not yet recruiting]
Nantes Cedex, France, 44035

[Not yet recruiting]
Paris, France, 75015

Germany, Baden-Württemberg

[Recruiting]
Freiburg, Baden-Württemberg, Germany, 79106

[Not yet recruiting]
Heidelberg, Baden-Württemberg, Germany, 69112

[Not yet recruiting]
Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

[Not yet recruiting]
München, Bayern, Germany, 81675

[Not yet recruiting]
Regensburg, Bayern, Germany, 93053

Germany, Nordrhein-Westfalen

[Not yet recruiting]
Aachen, Nordrhein-Westfalen, Germany, 52074

[Not yet recruiting]
Bonn, Nordrhein-Westfalen, Germany, 53105

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen, Germany, 40219

[Not yet recruiting]
Essen, Nordrhein-Westfalen, Germany, 45147

[Recruiting]
Köln, Nordrhein-Westfalen, Germany, 50931

[Not yet recruiting]
Köln, Nordrhein-Westfalen, Germany, 51109

[Not yet recruiting]
Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

[Not yet recruiting]
Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Sachsen

[Not yet recruiting]
Dresden, Sachsen, Germany, 01067

[Not yet recruiting]
Dresden, Sachsen, Germany, 01307

[Not yet recruiting]
Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

[Not yet recruiting]
Kiel, Schleswig-Holstein, Germany, 24105

Germany

[Not yet recruiting]
Berlin, Germany, 12200

[Not yet recruiting]
Hamburg, Germany, 20251

Hungary

[Not yet recruiting]
Budapest, Hungary, 1036

[Recruiting]
Budapest, Hungary, 1082

[Not yet recruiting]
Budapest, Hungary, 1106

[Not yet recruiting]
Veszprem, Hungary, 8200

India, Maharashtra

[Recruiting]
Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Recruiting]
Chennai, Tamil Nadu, India, 600 006

[Recruiting]
Coimbatore, Tamil Nadu, India, 641014

[Recruiting]
Madurai, Tamil Nadu, India, 625 020

[Recruiting]
Pondicherry, Tamil Nadu, India, 600007

India

[Not yet recruiting]
Bangalore, India, 560010

[Not yet recruiting]
Chandigarh, India, 160062

[Recruiting]
Gugarat, India

[Recruiting]
Hyderabad, India, 500 034

[Recruiting]
Kerala, India, 683572

[Not yet recruiting]
Kolkata, India, 700073

[Not yet recruiting]
Mumbai, India, 400 050

[Recruiting]
New Delhi, India, 110029

[Not yet recruiting]
Orissa, India, 751 024

Israel

[Not yet recruiting]
Afula, Israel, 18101

[Recruiting]
Jerusalem, Israel, 91120

[Recruiting]
Petach Tikva, Israel, 49100

[Not yet recruiting]
Rehovot, Israel, 76100

[Recruiting]
Tel Aviv, Israel, 64239

[Not yet recruiting]
Tel Hashomer, Israel, 52621

[Recruiting]
Zerifin, Israel, 70300

Italy

[Not yet recruiting]
Ancona, Italy, 60020

[Not yet recruiting]
Bari, Italy, 70124

[Not yet recruiting]
Catania, Italy

[Not yet recruiting]
Firenze, Italy, 50139

[Not yet recruiting]
Genova, Italy, 16132

[Not yet recruiting]
Milano, Italy, 20132

[Not yet recruiting]
Milano, Italy, 20142

[Not yet recruiting]
Padova, Italy, 35128

[Not yet recruiting]

Roma, Italy, 00133

[Not yet recruiting]
Roma, Italy, 00168

[Not yet recruiting]
Roma, Italy, 00198

[Not yet recruiting]
Siena, Italy, 53100

[Not yet recruiting]
Torino, Italy, 10126

[Not yet recruiting]
Trieste, Italy, 34100

[Not yet recruiting]
Udine, Italy, 33100

[Not yet recruiting]
Varese, Italy, 21100

Japan, Aichi

[Not yet recruiting]
Nagoya, Aichi, Japan, 466-8560

[Not yet recruiting]
Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Recruiting]
Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Not yet recruiting]
Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

[Not yet recruiting]
Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Not yet recruiting]
Kita, Kagawa, Japan, 761-0793

Japan, Osaka

[Not yet recruiting]
Hirakata, Osaka, Japan, 573-1191

[Not yet recruiting]
Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Not yet recruiting]
Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Not yet recruiting]
Chiyoda-ku, Tokyo, Japan, 101-8309

[Not yet recruiting]
Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

[Not yet recruiting]
Fukuoka, Japan, 812-8582

[Recruiting]
Fukushima, Japan, 960-1295

[Not yet recruiting]
Kagoshima, Japan, 890-8520

[Not yet recruiting]
Kyoto, Japan, 606-8507

Latvia

[Not yet recruiting]
Riga, Latvia, 1002

[Not yet recruiting]
Riga, Latvia, 1009

[Not yet recruiting]
Riga, Latvia

Mexico, DF

[Not yet recruiting]
Mexico City, DF, Mexico, 06800

[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Estado de México

[Not yet recruiting]
Metepec, Estado de México, Mexico, 52140

Mexico, Jalisco

[Not yet recruiting]
Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Not yet recruiting]
Monterrey, Nuevo Leon, Mexico, 64460

[Not yet recruiting]
Monterrey, Nuevo Leon, Mexico, 64060

Mexico

[Not yet recruiting]
Chihuahua, Mexico, 31238

[Not yet recruiting]

Mexico City, Mexico, 06030

[Not yet recruiting]
México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]
Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Not yet recruiting]
Nijmegen, EX, Netherlands, 6525

Netherlands

[Not yet recruiting]
Groningen, Netherlands, 9713 GZ

[Not yet recruiting]
Leiden, Netherlands, 2333 ZA

[Not yet recruiting]
Rotterdam, Netherlands, 3015 GD

Poland

[Not yet recruiting]
Gdansk, Poland, 80-952

[Not yet recruiting]
Katowice, Poland, 40-760

[Not yet recruiting]
Poznan, Poland, 61-848

[Terminated]
Sosnowiec, Poland, 41-200

[Not yet recruiting]
Warszawa, Poland, 00-416

[Not yet recruiting]
Warszawa, Poland, 00-621

[Not yet recruiting]
Warszawa, Poland, 01-755

[Not yet recruiting]
Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Not yet recruiting]
Wroclaw, Poland, 50-368

Portugal

[Not yet recruiting]
Coimbra, Portugal, 3000-548

[Not yet recruiting]
Lisboa, Portugal, 1649-035

[Not yet recruiting]
Porto, Portugal, 4200- 319

Slovakia

[Recruiting]
Banska Bystrica, Slovakia, 97517

[Not yet recruiting]
Bratislava, Slovakia, 81369

[Not yet recruiting]
Martin, Slovakia, 03659

Spain, Asturias

[Not yet recruiting]
Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15705

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15706

Spain

[Not yet recruiting]
Alicante, Spain, 03016

[Not yet recruiting]
Barcelona, Spain, 08017

[Not yet recruiting]
Barcelona, Spain, 08035

[Not yet recruiting]
Barcelona, Spain, 08036

[Not yet recruiting]
Madrid, Spain, 28002

[Not yet recruiting]
Madrid, Spain, 28040

[Not yet recruiting]
Madrid, Spain, 28046

[Not yet recruiting]
Malaga, Spain, 29010

[Not yet recruiting]
Pamplona, Spain, 31008

[Not yet recruiting]
Sevilla, Spain, 41013

[Not yet recruiting]
Sevilla, Spain, 41071

[Not yet recruiting]

Valencia, Spain, 46014

[Not yet recruiting]
Valencia, Spain, 46015

[Not yet recruiting]
Valladolid, Spain, 47005

Sweden

[Not yet recruiting]
Jönköping, Sweden, 551 85

[Not yet recruiting]
Linköping, Sweden, 58185

[Not yet recruiting]
Luleå, Sweden, 97180

[Not yet recruiting]
Stockholm, Sweden, 11282

[Terminated]
Uppsala, Sweden, 75185

[Not yet recruiting]
Örebro, Sweden, 70185

Switzerland

[Not yet recruiting]
Basel, Switzerland, 4031

[Not yet recruiting]
Bern, Switzerland, 3010

[Not yet recruiting]
Genève, Switzerland, 1211

[Not yet recruiting]
Zürich, Switzerland, 8091

United Kingdom, Greater London

[Not yet recruiting]

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Not yet recruiting]

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Northern Ireland

[Not yet recruiting]

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]

Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Not yet recruiting]

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Not yet recruiting]

Aberdeen, United Kingdom, AB25 2ZN

[Not yet recruiting]

Birmingham, United Kingdom, B4 7ET

[Not yet recruiting]

Dorchester, United Kingdom, DT1 2JY

[Not yet recruiting]

Liverpool, United Kingdom, L7 8XP

[Not yet recruiting]

London, United Kingdom, EC1V 2PD

[Not yet recruiting]

London, United Kingdom, NW1 5QH

[Not yet recruiting]
Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]
Oxford, United Kingdom, OX3 9DU

[Not yet recruiting]
Plymouth, United Kingdom, PL6 8BX

[Not yet recruiting]
Torquay, United Kingdom, TQ2 7AA

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls | Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2).

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight
3	○	○	June 19, 2008	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
4	◉	◉	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status
21	○	○	October 6, 2010	Study Status

Version	A	B	Submitted Date	Changes
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: August 4, 2008 (v4)

Study Identification

Unique Protocol ID: 91689

Brief Title: VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2).

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and

	Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).
Secondary IDs:	EurdaCT No.: 2007-000583-25 311523 VIEW 2

Study Status

Record Verification:	August 2008
Overall Status:	Recruiting
Study Start:	April 2008
Primary Completion:	September 2011 [Anticipated]
Study Completion:	September 2011 [Anticipated]
First Submitted:	March 12, 2008
First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	August 4, 2008
Last Update Posted:	August 5, 2008 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	
Collaborators:	Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

1. Signed informed consent.
2. Men and women ≥ 50 years of age.
3. Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
5. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
6. Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

1. Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
3. Any prior treatment with anti-VEGF agents in the study eye.
4. Total lesion size >12 disc areas (30.5 mm², including blood, scars and neovascularization) as assessed by FA in the study eye.
5. Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
6. Scar or fibrosis making up >50% of the total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
10. Presence of other causes of CNV in the study eye.
11. Prior vitrectomy in the study eye.
12. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
13. Any history of macular hole of stage 2 and above in the study eye.
14. Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
15. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Central Contact Backup: For trial location information (Phone Menu Options "3" or "4")
Telephone: (ex US: +1) 1-888-842-2937

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1122AAI

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Not yet recruiting]
Rosario, Santa Fe, Argentina, S2000ANJ

Argentina, Tucumán

[Not yet recruiting]
San Miguel de Tucumán, Tucumán, Argentina, 4000

Argentina

[Not yet recruiting]
Córdoba, Argentina, X5000IIT

Australia, New South Wales

[Not yet recruiting]
Westmead, New South Wales, Australia, 2145

Australia, Victoria

[Recruiting]
East Melbourne, Victoria, Australia, 3002

[Not yet recruiting]
Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]

Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]
Parramatta, Australia, 2150

Austria, Steiermark / 632

[Not yet recruiting]
Graz, Steiermark / 632, Austria, 8036

Austria, Tirol / 632

[Not yet recruiting]
Innsbruck, Tirol / 632, Austria, 6020

Austria

[Not yet recruiting]
Linz, Austria, 4021

[Recruiting]
Wien, Austria, 1090

Belgium

[Not yet recruiting]
Bruxelles, Belgium, 1070

[Not yet recruiting]
Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]
Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]
Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Not yet recruiting]
Araraquara, SP, Brazil, 14801-310

[Not yet recruiting]
Sao Paulo, SP, Brazil, 04023-900

Brazil

[Not yet recruiting]
Minas Gerais, Brazil, 30150-270

[Not yet recruiting]
Sao Paulo, Brazil, 05651-901

Colombia

[Not yet recruiting]
Bogota, Colombia

[Recruiting]
Cali, Colombia

[Not yet recruiting]
Medellín, Colombia

[Recruiting]
Medellín, Colombia

Czech Republic

[Not yet recruiting]
Brno, Czech Republic, 63400

[Not yet recruiting]
Hradec Kralove, Czech Republic, 500 05

[Not yet recruiting]
Olomouc, Czech Republic, 775 20

[Not yet recruiting]
Praha 4, Czech Republic, 14000

France, Cedex 12

[Not yet recruiting]
Paris, Cedex 12, France, 75557

France

[Not yet recruiting]
Besancon, France, 25030

[Not yet recruiting]
Bordeaux, France, 33000

[Not yet recruiting]
Dijon Cedex, France, BP 1542-21

[Not yet recruiting]
Grenoble, France, 38043

[Not yet recruiting]
Lyon, France, 69003

[Not yet recruiting]
Lyon, France, 69006

[Not yet recruiting]
Marseille, France, 13008

[Not yet recruiting]
Nantes Cedex, France, 44035

[Not yet recruiting]
Paris, France, 75015

Germany, Baden-Württemberg / 274

[Recruiting]
Freiburg, Baden-Württemberg / 274, Germany, 79106

Germany, Baden-Württemberg / 275

[Not yet recruiting]
Heidelberg, Baden-Württemberg / 275, Germany, 69112

Germany, Baden-Württemberg / 277

[Not yet recruiting]
Tübingen, Baden-Württemberg / 277, Germany, 72076

Germany, Bayern / 280

[Not yet recruiting]
München, Bayern / 280, Germany, 81675

[Not yet recruiting]
Regensburg, Bayern / 280, Germany, 93053

Germany, Berlin / 285

[Not yet recruiting]
Berlin, Berlin / 285, Germany, 12200

Germany, Hamburg / 287

[Not yet recruiting]
Hamburg, Hamburg / 287, Germany, 20251

Germany, Nordrhein-Westfalen / 296

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen / 296, Germany, 40219

Germany, Nordrhein-Westfalen / 297

[Not yet recruiting]
Köln, Nordrhein-Westfalen / 297, Germany, 50931

[Not yet recruiting]
Köln, Nordrhein-Westfalen / 297, Germany, 51109

Germany, Nordrhein-Westfalen / 298

[Not yet recruiting]
Münster, Nordrhein-Westfalen / 298, Germany, 48145

Germany, Nordrhein-Westfalen / 320

[Not yet recruiting]

Aachen, Nordrhein-Westfalen / 320, Germany, 52074

Germany, Nordrhein-Westfalen / 321

[Not yet recruiting]
Bonn, Nordrhein-Westfalen / 321, Germany, 53105

Germany, Nordrhein-Westfalen / 481

[Not yet recruiting]
Essen, Nordrhein-Westfalen / 481, Germany, 45147

Germany, Rheinland-Pfalz / 381

[Not yet recruiting]
Mainz, Rheinland-Pfalz / 381, Germany, 55131

Germany, Sachsen / 313

[Not yet recruiting]
Dresden, Sachsen / 313, Germany, 01067

[Not yet recruiting]
Dresden, Sachsen / 313, Germany, 01307

[Not yet recruiting]
Leipzig, Sachsen / 313, Germany, 04103

Germany, Schleswig-Holstein / 306

[Not yet recruiting]
Kiel, Schleswig-Holstein / 306, Germany, 24105

Hungary

[Not yet recruiting]
Budapest, Hungary, 1036

[Not yet recruiting]
Budapest, Hungary, 1082

[Not yet recruiting]
Budapest, Hungary, 1106

[Not yet recruiting]
Veszprem, Hungary, 8200

India, Maharashtra

[Recruiting]
Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Recruiting]
Chennai, Tamil Nadu, India, 600 006

[Recruiting]
Coimbatore, Tamil Nadu, India, 641014

[Recruiting]
Madurai, Tamil Nadu, India, 625 020

[Recruiting]
Pondicherry, Tamil Nadu, India, 600007

India

[Not yet recruiting]
Bangalore, India, 560010

[Not yet recruiting]
Chandigarh, India, 160062

[Recruiting]
Gugarat, India

[Recruiting]
Hyderabad, India, 500 034

[Not yet recruiting]
Kerala, India, 683572

[Not yet recruiting]
Kolkata, India, 700073

[Not yet recruiting]

Mumbai, India, 400 050

[Recruiting]
New Delhi, India, 110029

[Not yet recruiting]
Orissa, India, 751 024

Israel

[Not yet recruiting]
Afula, Israel, 18101

[Not yet recruiting]
Jerusalem, Israel, 91120

[Recruiting]
Petach Tikva, Israel, 49100

[Not yet recruiting]
Rehovot, Israel, 76100

[Not yet recruiting]
Tel Aviv, Israel, 64239

[Not yet recruiting]
Tel Hashomer, Israel, 52621

[Not yet recruiting]
Zerifin, Israel, 70300

Italy

[Not yet recruiting]
Ancona, Italy, 60020

[Not yet recruiting]
Bari, Italy, 70124

[Not yet recruiting]
Catania, Italy

[Not yet recruiting]

Firenze, Italy, 50139

[Not yet recruiting]
Genova, Italy, 16132

[Not yet recruiting]
Milano, Italy, 20132

[Not yet recruiting]
Milano, Italy, 20142

[Not yet recruiting]
Padova, Italy, 35128

[Not yet recruiting]
Roma, Italy, 00133

[Not yet recruiting]
Roma, Italy, 00168

[Not yet recruiting]
Roma, Italy, 00198

[Not yet recruiting]
Siena, Italy, 53100

[Not yet recruiting]
Torino, Italy, 10126

[Not yet recruiting]
Trieste, Italy, 34100

[Not yet recruiting]
Udine, Italy, 33100

[Not yet recruiting]
Varese, Italy, 21100

Japan, Aichi

[Not yet recruiting]
Nagoya, Aichi, Japan, 466-8560

[Not yet recruiting]
Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Recruiting]
Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Not yet recruiting]
Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

[Not yet recruiting]
Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Not yet recruiting]
Kita, Kagawa, Japan, 761-0793

Japan, Osaka

[Not yet recruiting]
Hirakata, Osaka, Japan, 573-1191

[Not yet recruiting]
Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Not yet recruiting]
Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Not yet recruiting]
ask Contact, Tokyo, Japan, 101-8309

[Not yet recruiting]
ask Contact, Tokyo, Japan, 160-8582

Japan

[Not yet recruiting]
Fukuoka, Japan, 812-8582

[Not yet recruiting]
Fukushima, Japan, 960-1295

[Not yet recruiting]
Kagoshima, Japan, 890-8520

[Not yet recruiting]
Kyoto, Japan, 606-8507

Latvia

[Not yet recruiting]
Riga, Latvia, 1002

[Not yet recruiting]
Riga, Latvia, 1009

[Not yet recruiting]
Riga, Latvia

Mexico, DF

[Not yet recruiting]
Mexico City, DF, Mexico, 06800

[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Estado de México

[Not yet recruiting]
Metepec, Estado de México, Mexico, 52140

Mexico, Jalisco

[Not yet recruiting]
Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Not yet recruiting]
Monterrey, Nuevo Leon, Mexico, 64460

Mexico

[Not yet recruiting]
Chihuahua, Mexico, 31238

[Not yet recruiting]
Mexico City, Mexico, 06030

[Not yet recruiting]
México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]
Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Not yet recruiting]
Nijmegen, EX, Netherlands, 6525

Netherlands

[Not yet recruiting]
Groningen, Netherlands, 9713 GZ

[Not yet recruiting]
Leiden, Netherlands, 2333 ZA

[Not yet recruiting]
Rotterdam, Netherlands, 3015 GD

Poland

[Not yet recruiting]
Gdansk, Poland, 80-952

[Not yet recruiting]

Katowice, Poland, 40-760

[Not yet recruiting]
Poznan, Poland, 61-848

[Not yet recruiting]
Warszawa, Poland, 00-416

[Not yet recruiting]
Warszawa, Poland, 00-621

[Not yet recruiting]
Warszawa, Poland, 01-755

[Not yet recruiting]
Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Not yet recruiting]
Wroclaw, Poland, 50-368

Portugal

[Not yet recruiting]
Coimbra, Portugal, 3000-548

[Not yet recruiting]
Lisboa, Portugal, 1649-035

[Not yet recruiting]
Porto, Portugal, 4200- 319

Slovakia

[Not yet recruiting]
Banska Bystrica, Slovakia, 97517

[Not yet recruiting]
Bratislava, Slovakia, 81369

[Not yet recruiting]

Martin, Slovakia, 03659

Spain, Asturias

[Not yet recruiting]
Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15705

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15706

Spain

[Not yet recruiting]
Alicante, Spain, 03016

[Not yet recruiting]
Barcelona, Spain, 08017

[Not yet recruiting]
Barcelona, Spain, 08035

[Not yet recruiting]
Barcelona, Spain, 08036

[Not yet recruiting]
Madrid, Spain, 28002

[Not yet recruiting]
Madrid, Spain, 28040

[Not yet recruiting]
Madrid, Spain, 28046

[Not yet recruiting]
Malaga, Spain, 29010

[Not yet recruiting]
Pamplona, Spain, 31008

[Not yet recruiting]
Sevilla, Spain, 41013

[Not yet recruiting]
Sevilla, Spain, 41071

[Not yet recruiting]
Valencia, Spain, 46014

[Not yet recruiting]
Valencia, Spain, 46015

[Not yet recruiting]
Valladolid, Spain, 47005

Sweden

[Not yet recruiting]
Jönköping, Sweden, 551 85

[Not yet recruiting]
Linköping, Sweden, 58185

[Not yet recruiting]
Luleå, Sweden, 97180

[Not yet recruiting]
Örebro, Sweden, 70185

[Not yet recruiting]
Stockholm, Sweden, 11282

Switzerland, Basel / 633

[Not yet recruiting]
Basel, Basel / 633, Switzerland, 4031

Switzerland, Genève / 633

[Not yet recruiting]
Genève, Genève / 633, Switzerland, 1211

Switzerland, Zürich / 633

[Not yet recruiting]
Zürich, Zürich / 633, Switzerland, 8091

Switzerland

[Not yet recruiting]
Bern, Switzerland, 3010

United Kingdom, Devon

[Not yet recruiting]
Torquay, Devon, United Kingdom, TQ2 7AA

United Kingdom, Greater London

[Not yet recruiting]
London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Not yet recruiting]
Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Northern Ireland

[Not yet recruiting]
Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]
Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Not yet recruiting]
Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Not yet recruiting]
Aberdeen, United Kingdom, AB25 2ZN

[Not yet recruiting]
Birmingham, United Kingdom, B4 7ET

[Not yet recruiting]
Liverpool, United Kingdom, L7 8XP

[Not yet recruiting]
London, United Kingdom, EC1V 2PD

[Not yet recruiting]
London, United Kingdom, NW1 5QH

[Not yet recruiting]
Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]
Oxford, United Kingdom, OX3 9DU

[Not yet recruiting]
Plymouth, United Kingdom, PL6 8BX

[Not yet recruiting]
Torquay, United Kingdom, TQ2 7AA

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2).

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight
3	◉	◉	June 19, 2008	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status
21	○	○	October 6, 2010	Study Status

Version	A	B	Submitted Date	Changes
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: June 19, 2008 (v3)

Study Identification

Unique Protocol ID: 91689

Brief Title: VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2).

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and

	Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).
Secondary IDs:	EurdaCT No.: 2007-000583-25 311523 VIEW 2

Study Status

Record Verification:	June 2008
Overall Status:	Recruiting
Study Start:	April 2008
Primary Completion:	
Study Completion:	September 2011 [Anticipated]
First Submitted:	March 12, 2008
First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	June 19, 2008
Last Update Posted:	June 20, 2008 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	
Collaborators:	Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

1. Signed informed consent.
2. Men and women ≥ 50 years of age.
3. Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
5. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
6. Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

1. Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
3. Any prior treatment with anti-VEGF agents in the study eye.
4. Total lesion size >12 disc areas (30.5 mm², including blood, scars and neovascularization) as assessed by FA in the study eye.
5. Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
6. Scar or fibrosis making up >50% of the total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
10. Presence of other causes of CNV in the study eye.
11. Prior vitrectomy in the study eye.
12. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
13. Any history of macular hole of stage 2 and above in the study eye.
14. Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
15. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Central Contact Backup: For trial location information (Phone Menu Options "3" or "4")
Telephone: (ex US: +1) 1-888-842-2937

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1122AAI

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Santa Fe

[Not yet recruiting]
Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

[Not yet recruiting]
Córdoba, Argentina, X5000IIT

Australia, New South Wales

[Not yet recruiting]
Westmead, New South Wales, Australia, 2145

Australia, Victoria

[Recruiting]
East Melbourne, Victoria, Australia, 3002

[Not yet recruiting]
Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]
Nedlands, Western Australia, Australia, 6009

Australia

[Recruiting]

Parramatta, Australia, 2150

Austria, Steiermark / 632

[Not yet recruiting]
Graz, Steiermark / 632, Austria, 8036

Austria, Tirol / 632

[Not yet recruiting]
Innsbruck, Tirol / 632, Austria, 6020

Austria

[Not yet recruiting]
Linz, Austria, 4021

[Not yet recruiting]
Wien, Austria, 1090

Belgium

[Not yet recruiting]
Bruxelles, Belgium, 1070

[Not yet recruiting]
Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]
Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]
Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Not yet recruiting]
Araraquara, SP, Brazil, 14801-310

[Not yet recruiting]

Sao Paulo, SP, Brazil, 04023-900

Brazil

[Not yet recruiting]
Minas Gerais, Brazil, 30150-270

[Not yet recruiting]
Sao Paulo, Brazil, 05651-901

Colombia

[Not yet recruiting]
Bogota, Colombia

[Not yet recruiting]
Cali, Colombia

[Not yet recruiting]
Medellín, Colombia

Czech Republic

[Not yet recruiting]
Brno, Czech Republic, 63400

[Not yet recruiting]
Hradec Kralove, Czech Republic, 500 05

[Not yet recruiting]
Olomouc, Czech Republic, 775 20

[Not yet recruiting]
Praha 4, Czech Republic, 14000

France, Cedex 12

[Not yet recruiting]
Paris, Cedex 12, France, 75557

France

[Not yet recruiting]

Besancon, France, 25030

[Not yet recruiting]
Bordeaux, France, 33000

[Not yet recruiting]
Dijon Cedex, France, BP 1542-21

[Not yet recruiting]
Grenoble, France, 38043

[Not yet recruiting]
Lyon, France, 69003

[Not yet recruiting]
Lyon, France, 69006

[Not yet recruiting]
Marseille, France, 13008

[Not yet recruiting]
Nantes Cedex, France, 44035

[Not yet recruiting]
Paris, France, 75015

Germany, Baden-Württemberg / 274

[Not yet recruiting]
Freiburg, Baden-Württemberg / 274, Germany, 79106

Germany, Baden-Württemberg / 275

[Not yet recruiting]
Heidelberg, Baden-Württemberg / 275, Germany, 69112

Germany, Baden-Württemberg / 277

[Not yet recruiting]
Tübingen, Baden-Württemberg / 277, Germany, 72076

Germany, Bayern / 280

[Not yet recruiting]
München, Bayern / 280, Germany, 81675

[Not yet recruiting]
Regensburg, Bayern / 280, Germany, 93053

Germany, Berlin / 285

[Not yet recruiting]
Berlin, Berlin / 285, Germany, 12200

Germany, Hamburg / 287

[Not yet recruiting]
Hamburg, Hamburg / 287, Germany, 20251

Germany, Nordrhein-Westfalen / 296

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen / 296, Germany, 40219

Germany, Nordrhein-Westfalen / 297

[Not yet recruiting]
Köln, Nordrhein-Westfalen / 297, Germany, 50931

[Not yet recruiting]
Köln, Nordrhein-Westfalen / 297, Germany, 51109

Germany, Nordrhein-Westfalen / 298

[Not yet recruiting]
Münster, Nordrhein-Westfalen / 298, Germany, 48145

Germany, Nordrhein-Westfalen / 320

[Not yet recruiting]
Aachen, Nordrhein-Westfalen / 320, Germany, 52074

Germany, Nordrhein-Westfalen / 321

[Not yet recruiting]
Bonn, Nordrhein-Westfalen / 321, Germany, 53105

Germany, Nordrhein-Westfalen / 481

[Not yet recruiting]
Essen, Nordrhein-Westfalen / 481, Germany, 45147

Germany, Rheinland-Pfalz / 381

[Not yet recruiting]
Mainz, Rheinland-Pfalz / 381, Germany, 55131

Germany, Sachsen / 313

[Not yet recruiting]
Dresden, Sachsen / 313, Germany, 01067

[Not yet recruiting]
Dresden, Sachsen / 313, Germany, 01307

[Not yet recruiting]
Leipzig, Sachsen / 313, Germany, 04103

Germany, Schleswig-Holstein / 306

[Not yet recruiting]
Kiel, Schleswig-Holstein / 306, Germany, 24105

Hungary

[Not yet recruiting]
Budapest, Hungary, 1036

[Not yet recruiting]
Budapest, Hungary, 1082

[Not yet recruiting]
Budapest, Hungary, 1106

[Not yet recruiting]
Veszprem, Hungary, 8200

India, Maharashtra

[Not yet recruiting]

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Not yet recruiting]
Chennai, Tamil Nadu, India, 600 006

[Not yet recruiting]
Coimbatore, Tamil Nadu, India, 641014

[Not yet recruiting]
Madurai, Tamil Nadu, India, 625 020

[Not yet recruiting]
Pondicherry, Tamil Nadu, India, 600007

India

[Not yet recruiting]
Bangalore, India, 560010

[Not yet recruiting]
Chandigarh, India, 160062

[Not yet recruiting]
Gugarat, India

[Not yet recruiting]
Hyderabad, India, 500 034

[Not yet recruiting]
Kerala, India, 683572

[Not yet recruiting]
Kolkata, India, 700073

[Not yet recruiting]
Mumbai, India, 400 050

[Not yet recruiting]
New Delhi, India, 110029

[Not yet recruiting]

Orissa, India, 751 024

Israel

[Not yet recruiting]
Afula, Israel, 18101

[Not yet recruiting]
Jerusalem, Israel, 91120

[Not yet recruiting]
Petach Tikva, Israel, 49100

[Not yet recruiting]
Rehovot, Israel, 76100

[Not yet recruiting]
Tel Aviv, Israel, 64239

[Not yet recruiting]
Tel Hashomer, Israel, 52621

[Not yet recruiting]
Zerifin, Israel, 70300

Italy

[Not yet recruiting]
Ancona, Italy, 60020

[Not yet recruiting]
Bari, Italy, 70124

[Not yet recruiting]
Catania, Italy

[Not yet recruiting]
Firenze, Italy, 50139

[Not yet recruiting]
Genova, Italy, 16132

[Not yet recruiting]

Milano, Italy, 20132

[Not yet recruiting]
Milano, Italy, 20142

[Not yet recruiting]
Padova, Italy, 35128

[Not yet recruiting]
Roma, Italy, 00133

[Not yet recruiting]
Roma, Italy, 00168

[Not yet recruiting]
Roma, Italy, 00198

[Not yet recruiting]
Siena, Italy, 53100

[Not yet recruiting]
Torino, Italy, 10126

[Not yet recruiting]
Trieste, Italy, 34100

[Not yet recruiting]
Udine, Italy, 33100

[Not yet recruiting]
Varese, Italy, 21100

Japan, Aichi

[Not yet recruiting]
Nagoya, Aichi, Japan, 466-8560

[Not yet recruiting]
Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Not yet recruiting]

Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Not yet recruiting]
Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

[Not yet recruiting]
Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Not yet recruiting]
Kita, Kagawa, Japan, 761-0793

Japan, Osaka

[Not yet recruiting]
Hirakata, Osaka, Japan, 573-1191

[Not yet recruiting]
Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Not yet recruiting]
Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

[Not yet recruiting]
ask Contact, Tokyo, Japan, 101-8309

Japan

[Not yet recruiting]
Fukuoka, Japan, 812-8582

[Not yet recruiting]
Fukushima, Japan, 960-1295

[Not yet recruiting]

Kagoshima, Japan, 890-8520

[Not yet recruiting]
Kyoto, Japan, 606-8507

[Not yet recruiting]
Tokyo, Japan, 160-8582

Latvia

[Not yet recruiting]
Riga, Latvia, 1002

[Not yet recruiting]
Riga, Latvia, 1009

[Not yet recruiting]
Riga, Latvia

Mexico, DF

[Not yet recruiting]
Mexico City, DF, Mexico, 06800

[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Estado de México

[Not yet recruiting]
Metepec, Estado de México, Mexico, 52140

Mexico, Jalisco

[Not yet recruiting]
Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Not yet recruiting]
Monterrey, Nuevo Leon, Mexico, 64460

Mexico

[Not yet recruiting]
Chihuahua, Mexico, 31238

[Not yet recruiting]
Mexico City, Mexico, 06030

[Not yet recruiting]
México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]
Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Not yet recruiting]
Nijmegen, EX, Netherlands, 6525

Netherlands

[Not yet recruiting]
Groningen, Netherlands, 9713 GZ

[Not yet recruiting]
Leiden, Netherlands, 2333 ZA

[Not yet recruiting]
Rotterdam, Netherlands, 3015 GD

Poland

[Not yet recruiting]
Gdansk, Poland, 80-952

[Not yet recruiting]
Katowice, Poland, 40-760

[Not yet recruiting]
Poznan, Poland, 61-848

[Not yet recruiting]
Warszawa, Poland, 00-416

[Not yet recruiting]
Warszawa, Poland, 00-621

[Not yet recruiting]
Warszawa, Poland, 01-755

[Not yet recruiting]
Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Not yet recruiting]
Wroclaw, Poland, 50-368

Portugal

[Not yet recruiting]
Coimbra, Portugal, 3000-548

[Not yet recruiting]
Lisboa, Portugal, 1649-035

[Not yet recruiting]
Porto, Portugal, 4200- 319

Slovakia

[Not yet recruiting]
Banska Bystrica, Slovakia, 97517

[Not yet recruiting]
Bratislava, Slovakia, 81369

[Not yet recruiting]
Martin, Slovakia, 03659

Spain, Asturias

[Not yet recruiting]
Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15705

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15706

Spain

[Not yet recruiting]
Alicante, Spain, 03016

[Not yet recruiting]
Barcelona, Spain, 08017

[Not yet recruiting]
Barcelona, Spain, 08035

[Not yet recruiting]
Barcelona, Spain, 08036

[Not yet recruiting]
Madrid, Spain, 28002

[Not yet recruiting]
Madrid, Spain, 28040

[Not yet recruiting]
Madrid, Spain, 28046

[Not yet recruiting]
Malaga, Spain, 29010

[Not yet recruiting]
Pamplona, Spain, 31008

[Not yet recruiting]
Sevilla, Spain, 41013

[Not yet recruiting]
Sevilla, Spain, 41071

[Not yet recruiting]
Valencia, Spain, 46014

[Not yet recruiting]
Valencia, Spain, 46015

[Not yet recruiting]
Valladolid, Spain, 47005

Sweden

[Not yet recruiting]
Jönköping, Sweden, 551 85

[Not yet recruiting]
Linköping, Sweden, 58185

[Not yet recruiting]
Luleå, Sweden, 97180

[Not yet recruiting]
Örebro, Sweden, 70185

[Not yet recruiting]
Stockholm, Sweden, 11282

Switzerland, Basel / 633

[Not yet recruiting]
Basel, Basel / 633, Switzerland, 4031

Switzerland, Genève / 633

[Not yet recruiting]
Genève, Genève / 633, Switzerland, 1211

Switzerland, Zürich / 633

[Not yet recruiting]
Zürich, Zürich / 633, Switzerland, 8091

Switzerland

[Not yet recruiting]

Bern, Switzerland, 3010

United Kingdom, Greater London

[Not yet recruiting]

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Not yet recruiting]

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Northern Ireland

[Not yet recruiting]

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

[Not yet recruiting]

Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Not yet recruiting]

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Not yet recruiting]

Aberdeen, United Kingdom, AB25 2ZN

[Not yet recruiting]

Birmingham, United Kingdom, B4 7ET

[Not yet recruiting]

Liverpool, United Kingdom, L7 8XP

[Not yet recruiting]

London, United Kingdom, EC1V 2PD

[Not yet recruiting]

London, United Kingdom, NW1 5QH

[Not yet recruiting]
Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]
Oxford, United Kingdom, OX3 9DU

[Not yet recruiting]
Plymouth, United Kingdom, PL6 8BX

[Not yet recruiting]
Torquay, United Kingdom, TQ2 7AA

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls | Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2).

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	◉	◉	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight
3	○	○	June 19, 2008	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status
21	○	○	October 6, 2010	Study Status

Version	A	B	Submitted Date	Changes
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: April 24, 2008 (v2)

Study Identification

Unique Protocol ID: 91689

Brief Title: VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2).

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and

	Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).
Secondary IDs:	EurdaCT No.: 2007-000583-25 311523 VIEW 2

Study Status

Record Verification:	April 2008
Overall Status:	Recruiting
Study Start:	April 2008
Primary Completion:	
Study Completion:	September 2011 [Anticipated]
First Submitted:	March 12, 2008
First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	April 24, 2008
Last Update Posted:	April 25, 2008 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	
Collaborators:	Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

1. Signed informed consent.
2. Men and women ≥ 50 years of age.
3. Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
5. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
6. Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

1. Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
3. Any prior treatment with anti-VEGF agents in the study eye.
4. Total lesion size >12 disc areas (30.5 mm², including blood, scars and neovascularization) as assessed by FA in the study eye.
5. Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
6. Scar or fibrosis making up >50% of the total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
10. Presence of other causes of CNV in the study eye.
11. Prior vitrectomy in the study eye.
12. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
13. Any history of macular hole of stage 2 and above in the study eye.
14. Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
15. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Central Contact Backup: For trial location information (Phone Menu Options "3" or "4")
Telephone: +1-888-84 22937

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Capital Federal**

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1015ABO

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1023AAQ

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1122AAI

[Not yet recruiting]
Buenos Aires, Capital Federal, Argentina, C1181ACH

Argentina, Córdoba

[Not yet recruiting]
Córdoba, Córdoba, Argentina, X5000IIT

Argentina, Santa Fe

[Not yet recruiting]
Rosario, Santa Fe, Argentina, S2000ANJ

Australia, New South Wales

[Not yet recruiting]
Westmead, New South Wales, Australia, 2145

Australia, Victoria

[Not yet recruiting]
East Melbourne, Victoria, Australia, 3002

[Not yet recruiting]
Parkville, Victoria, Australia, 3050

Australia, Western Australia

[Recruiting]
Nedlands, Western Australia, Australia, 6009

Australia

[Not yet recruiting]

Parramatta, Australia, 2150

Austria, Steiermark / 632

[Not yet recruiting]
Graz, Steiermark / 632, Austria, 8036

Austria, Tirol / 632

[Not yet recruiting]
Innsbruck, Tirol / 632, Austria, 6020

Austria

[Not yet recruiting]
Linz, Austria, 4021

[Not yet recruiting]
Wien, Austria, 1090

Belgium

[Not yet recruiting]
Bruxelles, Belgium, 1070

[Not yet recruiting]
Liege, Belgium, 4000

Brazil, Centro-oeste

[Not yet recruiting]
Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

[Not yet recruiting]
Londrina, Paraná, Brazil, 86038440

Brazil, SP

[Not yet recruiting]
Araraquara, SP, Brazil, 14801-310

[Not yet recruiting]

Sao Paulo, SP, Brazil, 04023-900

Brazil

[Not yet recruiting]
Minas Gerais, Brazil, 30150-270

[Not yet recruiting]
Sao Paulo, Brazil, 05651-901

Colombia

[Not yet recruiting]
Bogota, Colombia

[Not yet recruiting]
Cali, Colombia

[Not yet recruiting]
Medellín, Colombia

Czech Republic

[Not yet recruiting]
Brno, Czech Republic, 63400

[Not yet recruiting]
Hradec Kralove, Czech Republic, 500 05

[Not yet recruiting]
Olomouc, Czech Republic, 775 20

[Not yet recruiting]
Praha 4, Czech Republic, 14000

France, Cedex 12

[Not yet recruiting]
Paris, Cedex 12, France, 75557

France

[Not yet recruiting]

Besancon, France, 25030

[Not yet recruiting]
Bordeaux, France, 33000

[Not yet recruiting]
Dijon Cedex, France, BP 1542-21

[Not yet recruiting]
Grenoble, France, 38043

[Not yet recruiting]
Lyon, France, 69003

[Not yet recruiting]
Lyon, France, 69006

[Not yet recruiting]
Marseille, France, 13008

[Not yet recruiting]
Nantes Cedex, France, 44035

[Not yet recruiting]
Paris, France, 75015

Germany, Baden-Württemberg / 274

[Not yet recruiting]
Freiburg, Baden-Württemberg / 274, Germany, 79106

Germany, Baden-Württemberg / 275

[Not yet recruiting]
Heidelberg, Baden-Württemberg / 275, Germany, 69112

Germany, Baden-Württemberg / 277

[Not yet recruiting]
Tübingen, Baden-Württemberg / 277, Germany, 72076

Germany, Bayern / 280

[Not yet recruiting]
München, Bayern / 280, Germany, 81675

[Not yet recruiting]
Regensburg, Bayern / 280, Germany, 93053

Germany, Berlin / 285

[Not yet recruiting]
Berlin, Berlin / 285, Germany, 12200

Germany, Hamburg / 287

[Not yet recruiting]
Hamburg, Hamburg / 287, Germany, 20251

Germany, Nordrhein-Westfalen / 296

[Not yet recruiting]
Düsseldorf, Nordrhein-Westfalen / 296, Germany, 40219

Germany, Nordrhein-Westfalen / 297

[Not yet recruiting]
Köln, Nordrhein-Westfalen / 297, Germany, 50931

[Not yet recruiting]
Köln, Nordrhein-Westfalen / 297, Germany, 50996

[Not yet recruiting]
Köln, Nordrhein-Westfalen / 297, Germany, 51109

Germany, Nordrhein-Westfalen / 298

[Not yet recruiting]
Münster, Nordrhein-Westfalen / 298, Germany, 48145

Germany, Nordrhein-Westfalen / 320

[Not yet recruiting]
Aachen, Nordrhein-Westfalen / 320, Germany, 52074

Germany, Nordrhein-Westfalen / 321

[Not yet recruiting]

Bonn, Nordrhein-Westfalen / 321, Germany, 53105

Germany, Nordrhein-Westfalen / 481

[Not yet recruiting]

Essen, Nordrhein-Westfalen / 481, Germany, 45147

Germany, Rheinland-Pfalz / 381

[Not yet recruiting]

Mainz, Rheinland-Pfalz / 381, Germany, 55131

Germany, Sachsen / 313

[Not yet recruiting]

Dresden, Sachsen / 313, Germany, 01067

[Not yet recruiting]

Dresden, Sachsen / 313, Germany, 01307

[Not yet recruiting]

Leipzig, Sachsen / 313, Germany, 04103

Germany, Schleswig-Holstein / 306

[Not yet recruiting]

Kiel, Schleswig-Holstein / 306, Germany, 24105

Hungary

[Not yet recruiting]

Budapest, Hungary, 1036

[Not yet recruiting]

Budapest, Hungary, 1082

[Not yet recruiting]

Budapest, Hungary, 1106

[Not yet recruiting]

Veszprem, Hungary, 8200

India, Maharashtra

[Not yet recruiting]
Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

[Not yet recruiting]
Chennai, Tamil Nadu, India, 600 006

[Not yet recruiting]
Coimbatore, Tamil Nadu, India, 641014

[Not yet recruiting]
Madurai, Tamil Nadu, India, 625 020

[Not yet recruiting]
Pondicherry, Tamil Nadu, India, 600007

India

[Not yet recruiting]
Bangalore, India, 560010

[Not yet recruiting]
Chandigarh, India, 160062

[Not yet recruiting]
Gujarat, India

[Not yet recruiting]
Hyderabaad, India, 500 034

[Not yet recruiting]
Kerala, India, 683572

[Not yet recruiting]
Kolkata, India, 700073

[Not yet recruiting]
New Delhi, India, 110029

[Not yet recruiting]

Orissa, India, 751 024

Israel

[Not yet recruiting]
Afula, Israel, 18101

[Not yet recruiting]
Jerusalem, Israel, 91120

[Not yet recruiting]
Petach Tikva, Israel, 49100

[Not yet recruiting]
Rehovot, Israel, 76100

[Not yet recruiting]
Tel Aviv, Israel, 64239

[Not yet recruiting]
Tel Hashomer, Israel, 52621

[Not yet recruiting]
Zerifin, Israel, 70300

Italy

[Not yet recruiting]
Ancona, Italy, 60020

[Not yet recruiting]
Bari, Italy, 70124

[Not yet recruiting]
Catania, Italy

[Not yet recruiting]
Firenze, Italy, 50139

[Not yet recruiting]
Genova, Italy, 16132

[Not yet recruiting]

Milano, Italy, 20132

[Not yet recruiting]
Milano, Italy, 20142

[Not yet recruiting]
Padova, Italy, 35128

[Not yet recruiting]
Roma, Italy, 00133

[Not yet recruiting]
Roma, Italy, 00168

[Not yet recruiting]
Roma, Italy, 00198

[Not yet recruiting]
Siena, Italy, 53100

[Not yet recruiting]
Torino, Italy, 10126

[Not yet recruiting]
Trieste, Italy, 34100

[Not yet recruiting]
Udine, Italy, 33100

[Not yet recruiting]
Varese, Italy, 21100

Japan, Aichi

[Not yet recruiting]
Nagoya, Aichi, Japan, 466-8560

[Not yet recruiting]
Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

[Not yet recruiting]

Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

[Not yet recruiting]
Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

[Not yet recruiting]
Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

[Not yet recruiting]
Kita, Kagawa, Japan, 761-0793

Japan, Osaka

[Not yet recruiting]
Hirakata, Osaka, Japan, 573-1191

[Not yet recruiting]
Suita, Osaka, Japan, 565-0871

Japan, Shiga

[Not yet recruiting]
Otsu, Shiga, Japan, 520-2192

Japan

[Not yet recruiting]
Fukuoka, Japan, 812-8582

[Not yet recruiting]
Fukushima, Japan, 960-1295

[Not yet recruiting]
Kagoshima, Japan, 890-8520

[Not yet recruiting]
Kyoto, Japan, 606-8507

[Not yet recruiting]
Tokyo, Japan, 101-8309

[Not yet recruiting]
Tokyo, Japan, 160-8582

Latvia

[Not yet recruiting]
Riga, Latvia, 1002

[Not yet recruiting]
Riga, Latvia, 1009

[Not yet recruiting]
Riga, Latvia

Mexico, DF

[Not yet recruiting]
Mexico City, DF, Mexico, 06800

[Not yet recruiting]
Mexico City, DF, Mexico, 14080

Mexico, Estado de México

[Not yet recruiting]
Metepec, Estado de México, Mexico, 52140

Mexico, Jalisco

[Not yet recruiting]
Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

[Not yet recruiting]
Monterrey, Nuevo Leon, Mexico, 64460

Mexico

[Not yet recruiting]

Chihuahua, Mexico, 31238

[Not yet recruiting]
Mexico City, Mexico, 06030

[Not yet recruiting]
México D.F., Mexico, 04030

Netherlands, DD

[Not yet recruiting]
Amsterdam, DD, Netherlands, 1100

Netherlands, EX

[Not yet recruiting]
Nijmegen, EX, Netherlands, 6525

Netherlands

[Not yet recruiting]
Groningen, Netherlands, 9713 GZ

[Not yet recruiting]
Leiden, Netherlands, 2333 ZA

[Not yet recruiting]
Rotterdam, Netherlands, 3015 GD

Poland

[Not yet recruiting]
Gdansk, Poland, 80-952

[Not yet recruiting]
Katowice, Poland, 40-760

[Not yet recruiting]
Poznan, Poland, 61-848

[Not yet recruiting]
Warszawa, Poland, 00-416

[Not yet recruiting]
Warszawa, Poland, 00-621

[Not yet recruiting]
Warszawa, Poland, 01-755

[Not yet recruiting]
Warszawa, Poland, 02-005

[Not yet recruiting]
Warszawa, Poland, 03-709

[Not yet recruiting]
Wroclaw, Poland, 50-368

Portugal

[Not yet recruiting]
Coimbra, Portugal, 3000-548

[Not yet recruiting]
Lisboa, Portugal, 1649-035

[Not yet recruiting]
Porto, Portugal, 4200- 319

Slovakia

[Not yet recruiting]
Banska Bystrica, Slovakia, 97517

[Not yet recruiting]
Bratislava, Slovakia, 81369

[Not yet recruiting]
Martin, Slovakia, 03659

Spain, Asturias

[Not yet recruiting]
Oviedo, Asturias, Spain, 33012

Spain, La Coruna

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15705

[Not yet recruiting]
Santiago de Compostela, La Coruna, Spain, 15706

Spain, Madrid

[Not yet recruiting]
Aravaca, Madrid, Spain, 28023

Spain

[Not yet recruiting]
Alicante, Spain, 03016

[Not yet recruiting]
Barcelona, Spain, 08017

[Not yet recruiting]
Barcelona, Spain, 08035

[Not yet recruiting]
Barcelona, Spain, 08036

[Not yet recruiting]
Madrid, Spain, 28002

[Not yet recruiting]
Madrid, Spain, 28040

[Not yet recruiting]
Madrid, Spain, 28046

[Not yet recruiting]
Malaga, Spain, 29010

[Not yet recruiting]
Pamplona, Spain, 31008

[Not yet recruiting]
Sevilla, Spain, 41013

[Not yet recruiting]
Sevilla, Spain, 41071

[Not yet recruiting]
Valencia, Spain, 46014

[Not yet recruiting]
Valencia, Spain, 46015

[Not yet recruiting]
Valladolid, Spain, 47005

Sweden

[Not yet recruiting]
Jönköping, Sweden, 551 85

[Not yet recruiting]
Linköping, Sweden, 58185

[Not yet recruiting]
Luleå, Sweden, 97180

[Not yet recruiting]
Örebro, Sweden, 70185

[Not yet recruiting]
Stockholm, Sweden, 11282

Switzerland, Basel / 633

[Not yet recruiting]
Basel, Basel / 633, Switzerland, 4031

Switzerland, Genève / 633

[Not yet recruiting]
Genève, Genève / 633, Switzerland, 1211

Switzerland, Zürich / 633

[Not yet recruiting]
Zürich, Zürich / 633, Switzerland, 8091

Switzerland

[Not yet recruiting]

Bern, Switzerland, 3010

United Kingdom, Greater London

[Not yet recruiting]

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

[Not yet recruiting]

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Northern Ireland

[Not yet recruiting]

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Oxfordshire

[Not yet recruiting]

Bicester, Oxfordshire, United Kingdom, OX26 4JT

United Kingdom, Scotland

[Not yet recruiting]

Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

[Not yet recruiting]

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

[Not yet recruiting]

Aberdeen, United Kingdom, AB25 2ZN

[Not yet recruiting]

Birmingham, United Kingdom, B4 7ET

[Not yet recruiting]

Liverpool, United Kingdom, L7 8XP

[Not yet recruiting]
London, United Kingdom, EC1V 2PD

[Not yet recruiting]
London, United Kingdom, NW1 5QH

[Not yet recruiting]
Newcastle upon Tyne, United Kingdom, NE1 4LP

[Not yet recruiting]
Oxford, United Kingdom, OX3 9DU

[Not yet recruiting]
Plymouth, United Kingdom, PL6 8BX

[Not yet recruiting]
Torquay, United Kingdom, TQ2 7AA

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2).

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	◉	◉	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight
3	○	○	June 19, 2008	Contacts/Locations and Study Status

Version	A	B	Submitted Date	Changes
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status
21	○	○	October 6, 2010	Study Status

Version	A	B	Submitted Date	Changes
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: March 17, 2008 (v1)

Study Identification

Unique Protocol ID: 91689

Brief Title: VEGF Trap-Eye: Investigation of Efficacy and Safety in Wet AMD (VIEW 2).

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and

	Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD).
Secondary IDs:	EurdaCT No.: 2007-000583-25 311523 VIEW 2

Study Status

Record Verification:	March 2008
Overall Status:	Not yet recruiting
Study Start:	March 2008
Primary Completion:	
Study Completion:	September 2011 [Anticipated]
First Submitted:	March 12, 2008
First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	March 17, 2008
Last Update Posted:	March 18, 2008 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	
Collaborators:	Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	

Data Monitoring: Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description:

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Experimental: Arm 3	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 8 weeks (including one additional 2,0 mg dose at Week 4) during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 1	Drug: VEGF Trap-Eye 0.5 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Arm 2	Drug: VEGF Trap-Eye 2.0 mg VEGF Trap-Eye administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Active Comparator: Arm 4	Drug: Ranibizumab 0.5 mg administered every 4 weeks during the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

Primary Outcome Measures:

1. The proportion of subjects who maintain vision at Week 52, where a subject is classified as maintaining vision if the subject has lost fewer than 15 letters on the ETDRS chart compared to baseline (ie, prevention of moderate vision loss)
   Week 52

Secondary Outcome Measures:

2. Mean change from baseline in BCVA as measured by ETDRS letter score at Week 52
   Week 52

3. The proportion of subjects who gain at least 15 letters of vision at Week 52
   Week 52
4. Mean change from baseline in total NEI VFQ-25 score at Week 52
   Week 52
5. Mean change from baseline in CNV area at Week 52
   Week 52

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

1. Signed informed consent.
2. Men and women ≥ 50 years of age.
3. Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by FA in the study eye.
4. ETDRS best-corrected visual acuity of: 20/40 to 20/320 (letter score of 73 to 25) in the study eye at 4 meters.
5. Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
6. Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

1. Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

2. Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
3. Any prior treatment with anti-VEGF agents in the study eye.
4. Total lesion size >12 disc areas (30.5 mm², including blood, scars and neovascularization) as assessed by FA in the study eye.
5. Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
6. Scar or fibrosis making up >50% of the total lesion in the study eye.
7. Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
8. Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
9. History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
10. Presence of other causes of CNV in the study eye.
11. Prior vitrectomy in the study eye.
12. History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
13. Any history of macular hole of stage 2 and above in the study eye.
14. Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
15. History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Central Contact: Bayer Clinical Trials Contact
Email: clinical-trials-contact@bayerhealthcare.com

Central Contact Backup: For trial location information (Phone Menu Options \\
Telephone: +1-888-84 22937

Study Officials: Study Director Bayer Study Manager
Study Director
Bayer

Locations: **Argentina, Capital Federal**

Buenos Aires, Capital Federal, Argentina, C1015ABO

Buenos Aires, Capital Federal, Argentina, C1023AAQ

Buenos Aires, Capital Federal, Argentina, C1120AAN

Buenos Aires, Capital Federal, Argentina, C1122AAI

Argentina, Córdoba

Córdoba, Córdoba, Argentina, X5000IIT

Argentina, Santa Fe

Rosario, Santa Fe, Argentina, 1288

Argentina

Buenos Aires, Argentina, C1181ACH

Australia, New South Wales

Westmead, New South Wales, Australia, 2145

Australia, Victoria

East Melbourne, Victoria, Australia, 3002

Parkville, Victoria, Australia, 3050

Australia, Western Australia

Nedlands, Western Australia, Australia, 6009

Australia

Parramatta, Australia, 2150

Austria, Steiermark / 632

Graz, Steiermark / 632, Austria, 8036

Austria, Tirol / 632

Innsbruck, Tirol / 632, Austria, 6020

Austria

Linz, Austria, 4021

Salzburg, Austria, 5020

Wien, Austria, 1090

Belgium

Bruxelles, Belgium, 1070

Liege, Belgium, 4000

Brazil, Centro-oeste

Goiania, Centro-oeste, Brazil, 74210-010

Brazil, Paraná

Londrina, Paraná, Brazil, 86038440

Brazil, SP

Araraquara, SP, Brazil, 14801-310

Sao Paulo, SP, Brazil, 04023-900

Brazil

Belo Horizonte, Brazil, 30150-270

Sao Paulo, Brazil, 05651-901

Colombia

Bogota, Colombia

Cali, Colombia

Medellín, Colombia

Czech Republic

Brno, Czech Republic, 63400

Hradec Kralove, Czech Republic, 500 05

Olomouc, Czech Republic, 775 20

Praha 4, Czech Republic, 14000

France, Cedex 12

Paris, Cedex 12, France, 75557

France

Besancon, France, 25030

Bordeaux, France, 33000

Dijon Cedex, France, BP 1542-21

Grenoble, France, 38043

Lyon, France, 69003

Lyon, France, 69006

Marseille, France, 13008

Nantes Cedex, France, 44035

Paris, France, 75015

Germany, Baden-Württemberg / 274

Freiburg, Baden-Württemberg / 274, Germany, 79106

Germany, Baden-Württemberg / 275

Heidelberg, Baden-Württemberg / 275, Germany, 69112

Germany, Baden-Württemberg / 277

Tübingen, Baden-Württemberg / 277, Germany, 72076

Germany, Bayern / 280

Erlangen, Bayern / 280, Germany, 91054

München, Bayern / 280, Germany, 81675

Regensburg, Bayern / 280, Germany, 93053

Germany, Berlin / 285

Berlin, Berlin / 285, Germany, 12200

Germany, Hamburg / 287

Hamburg, Hamburg / 287, Germany, 20251

Germany, Nordrhein-Westfalen / 296

Düsseldorf, Nordrhein-Westfalen / 296, Germany, 40219

Germany, Nordrhein-Westfalen / 297

Köln, Nordrhein-Westfalen / 297, Germany, 50931

Köln, Nordrhein-Westfalen / 297, Germany, 50996

Köln, Nordrhein-Westfalen / 297, Germany, 51109

Germany, Nordrhein-Westfalen / 298

Münster, Nordrhein-Westfalen / 298, Germany, 48145

Germany, Nordrhein-Westfalen / 320

Aachen, Nordrhein-Westfalen / 320, Germany, 52074

Germany, Nordrhein-Westfalen / 321

Bonn, Nordrhein-Westfalen / 321, Germany, 53105

Germany, Nordrhein-Westfalen / 481

Essen, Nordrhein-Westfalen / 481, Germany, 45147

Germany, Nordrhein-Westfalen / 504

Duisburg, Nordrhein-Westfalen / 504, Germany, 47119

Germany, Rheinland-Pfalz / 381

Mainz, Rheinland-Pfalz / 381, Germany, 55131

Germany, Sachsen / 313

Dresden, Sachsen / 313, Germany, 01307

Leipzig, Sachsen / 313, Germany, 04103

Germany, Schleswig-Holstein / 306

Kiel, Schleswig-Holstein / 306, Germany, 24105

Hungary

Budapest, Hungary, 1036

Budapest, Hungary, 1082

Budapest, Hungary, 1106

Veszprem, Hungary, 8200

India, Tamil Nadu

Chennai, Tamil Nadu, India, 600 006

Coimbatore, Tamil Nadu, India, 641014

Madurai, Tamil Nadu, India, 625 020

Pondicherry, Tamil Nadu, India, 600007

India

Bangalore, India, 560010

Chandigarh, India, 160062

Gujarat, India

Hyderabaad, India, 500 034

Kerala, India, 683572

Kolkata, India, 700073

Mumbai, India, 400031

New Delhi, India, 110029

Orissa, India, 751 024

Israel

Afula, Israel, 18101

Jerusalem, Israel, 91120

Petach Tikva, Israel, 49100

Rehovot, Israel, 76100

Tel Aviv, Israel, 64239

Tel Hashomer, Israel, 52621

Zerifin, Israel, 70300

Italy

Ancona, Italy, 60020

Bari, Italy, 70124

Catania, Italy

Firenze, Italy, 50139

Genova, Italy, 16132

Milano, Italy, 20132

Milano, Italy, 20142

Padova, Italy, 35128

Roma, Italy, 00133

Roma, Italy, 00168

Roma, Italy, 00198

Siena, Italy, 53100

Torino, Italy, 10126

Trieste, Italy, 34100

Udine, Italy, 33100

Varese, Italy, 21100

Japan, Aichi

Nagoya, Aichi, Japan, 466-8560

Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

Kida, Kagawa, Japan, 761-0793

Japan, Osaka

Hirakata, Osaka, Japan, 573-1191

Suita, Osaka, Japan, 565-0871

Japan, Shiga

Otsu, Shiga, Japan, 520-2192

Japan

Fukuoka, Japan, 812-8582

Fukushima, Japan, 960-1295

Kagoshima, Japan, 890-8520

Kyoto, Japan, 606-8507

Tokyo, Japan, 101-8309

Tokyo, Japan, 160-8582

Latvia

Riga, Latvia, 1002

Riga, Latvia, 1009

Riga, Latvia

Mexico, DF

Mexico City, DF, Mexico, 06800

Mexico City, DF, Mexico, 14080

Mexico, Estado de México

Metepec, Estado de México, Mexico, 52140

Mexico, Jalisco

Zapopan, Jalisco, Mexico, 45060

Mexico, Nuevo Leon

Monterrey, Nuevo Leon, Mexico, 64460

Mexico

Chihuahua, Mexico, 31238

Mexico City, Mexico, 06030

Mexico, D.F., Mexico, 04030

Netherlands, DD

Amsterdam, DD, Netherlands, 1100

Netherlands, EX

Nijmegen, EX, Netherlands, 6525

Netherlands, Noord Brabant

Eindhoven, Noord Brabant, Netherlands, 5623 EJ

Netherlands

Groningen, Netherlands, 9713 GZ

Leiden, Netherlands, 2333 ZA

Rotterdam, Netherlands, 3015 GD

Poland

Gdansk, Poland, 80-952

Katowice, Poland, 40-760

Poznan, Poland, 61-848

Warszawa, Poland, 00-416

Warszawa, Poland, 00-621

Warszawa, Poland, 01-755

Warszawa, Poland, 02-005

Warszawa, Poland, 03-709

Wroclaw, Poland, 50-368

Portugal

Coimbra, Portugal, 3000-548

Lisboa, Portugal, 1649-035

Porto, Portugal, 4200- 319

Slovakia

Banska Bystrica, Slovakia, 97517

Bratislava, Slovakia, 81369

Martin, Slovakia, 03659

Spain, Asturias

Oviedo, Asturias, Spain, 33012

Spain, La Coruna

Santiago de Compostela, La Coruna, Spain, 15705

Santiago de Compostela, La Coruna, Spain, 15706

Spain, Madrid

Aravaca, Madrid, Spain, 28023

Spain

Alicante, Spain, 03016

Barcelona, Spain, 08017

Barcelona, Spain, 08035

Barcelona, Spain, 08036

Madrid, Spain, 28002

Madrid, Spain, 28040

Madrid, Spain, 28046

Malaga, Spain, 29010

Pamplona, Spain, 31008

Sevilla, Spain, 41013

Sevilla, Spain, 41071

Valencia, Spain, 46014

Valencia, Spain, 46015

Valladolid, Spain, 47005

Sweden

Jönköping, Sweden, 551 85

Linköping, Sweden, 58185

Luleå, Sweden, 97180

Örebro, Sweden, 70185

Stockholm, Sweden, 11282

Switzerland, Basel / 633

Basel, Basel / 633, Switzerland, 4031

Switzerland, Genève / 633

Genève, Genève / 633, Switzerland, 1211

Switzerland, Zürich / 633

Zürich, Zürich / 633, Switzerland, 8091

Switzerland

Bern, Switzerland, 3010

United Kingdom, Greater London

London, Greater London, United Kingdom, SE5 9RS

United Kingdom, Hampshire

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Northern Ireland

Belfast, Northern Ireland, United Kingdom, BT9 7BL

United Kingdom, Scotland

Edinburgh, Scotland, United Kingdom, EH3 9HA

United Kingdom, Surrey

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

Aberdeen, United Kingdom, AB25 2ZN

Birmingham, United Kingdom, B4 7ET

Liverpool, United Kingdom, L7 8XP

London, United Kingdom, EC1V 2PD

London, United Kingdom, NW1 5QH

Manchester, United Kingdom, M13 9PT

Newcastle upon Tyne, United Kingdom, NE1 4LP

Oxford, United Kingdom, OX3 9DU

Plymouth, United Kingdom, PL6 8BX

Torquay, United Kingdom, TQ2 7AA

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes

Regeneron Ex. 2001
Fresenius v. Regeneron
IPR2025-01269
Page 2651 of 3000

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility

Version	A	B	Submitted Date	Changes
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	◉	◉	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: (•) Merged ( ) Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: November 28, 2014 (v30)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD)

Secondary IDs: 2007-000583-25 [EudraCT Number]

Study Status

Record Verification: November 2014

Overall Status: Completed

Study Start: April 2008

Primary Completion: September 2010 [Actual]

Study Completion: August 2011 [Actual]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Results First Submitted:	December 16, 2011
Results First Submitted that Met QC Criteria:	December 16, 2011
Results First Posted:	January 23, 2012 [Estimate]
Last Update Submitted that Met QC Criteria:	November 28, 2014
Last Update Posted:	December 12, 2014 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	Sponsor
Collaborators:	Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description: Data of this trial ("VIEW 2") was pooled with data of a sister trial ("VIEW 1", NCT00509795), and an integrated analyses of the combined data was performed.

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1240 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Active Comparator: Ranibizumab 0.5mg Q4 Participants received a 0.5 mg dose of Ranibizumab via intravitreal (IVT) injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Drug: Ranibizumab Participants received a 0.5 mg dose of Ranibizumab via intravitreal (IVT) injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4 Participants received a 2.0 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 2.0 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4 Participants received a 0.5 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 0.5 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8 Participants received a 2.0 mg dose of Aflibercept Injection administered every 8 weeks (including one additional 2,0 mg dose at Week 4) for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 2.0 mg dose of Aflibercept Injection administered every 8 weeks (including one additional 2,0 mg dose at Week 4) for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by Fluorescein angiography (FA) in the study eye.
- ETDRS Best-Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Ciudad Auton. de Buenos Aires**

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1015ABO

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1023AAQ

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1122AAI

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1181ACH

Argentina, Santa Fe

Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

Córdoba, Argentina, X5000IIT

Australia, New South Wales

Chatswood, New South Wales, Australia, 2067

Sydney, New South Wales, Australia, 2000

Westmead, New South Wales, Australia, 2145

Australia, Victoria

East Melbourne, Victoria, Australia, 3002

Parkville, Victoria, Australia, 3050

Australia, Western Australia

Nedlands, Western Australia, Australia, 6009

Australia

Parramatta, Australia, 2150

Austria

Innsbruck, Austria, 6020

Linz, Austria, 4021

Wien, Austria, 1090

Belgium

Liege, Belgium, 4000

Brazil, Sao Paulo

Ribeirão Preto, Sao Paulo, Brazil, 14048-900

São Paulo, Sao Paulo, Brazil, 05651-901

Brazil

Minas Gerais, Brazil, 30150-270

Sao Paulo, Brazil, 04023-062

Colombia, Antioquia

Medellín, Antioquia, Colombia

Colombia, Cauca

Cali, Cauca, Colombia

Colombia, Distrito Capital de Bogotá

Bogota, Distrito Capital de Bogotá, Colombia

Czech Republic

Brno, Czech Republic, 63400

Olomouc, Czech Republic, 77520

Praha 10, Czech Republic, 10034

Praha 4, Czech Republic, 14000

Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

Paris, Cedex 12, France, 75557

France, Cedex 1

Nantes, Cedex 1, France, 44093

France

Besancon, France, 25030

Bordeaux, France, 33000

Dijon, France, 21079

Lyon, France, 69003

Lyon, France, 69006

Marseille, France, 13008

Paris, France, 75010

Paris, France, 75015

Germany, Baden-Württemberg

Freiburg, Baden-Württemberg, Germany, 79106

Heidelberg, Baden-Württemberg, Germany, 69120

Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

München, Bayern, Germany, 81675

Regensburg, Bayern, Germany, 93053

Germany, Hessen

Darmstadt, Hessen, Germany, 64297

Germany, Nordrhein-Westfalen

Aachen, Nordrhein-Westfalen, Germany, 52074

Bonn, Nordrhein-Westfalen, Germany, 53105

Essen, Nordrhein-Westfalen, Germany, 45122

Köln, Nordrhein-Westfalen, Germany, 50924

Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

Ludwigshafen, Rheinland-Pfalz, Germany, 67063

Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

Homburg, Saarland, Germany, 66421

Germany, Sachsen

Dresden, Sachsen, Germany, 01307

Dresden, Sachsen, Germany, 06067

Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

Kiel, Schleswig-Holstein, Germany, 24105

Lübeck, Schleswig-Holstein, Germany, 23538

Germany

Berlin, Germany, 12200

Hamburg, Germany, 20251

Hungary

Budapest, Hungary, 1083

Budapest, Hungary, 1106

Budapest, Hungary, 1133

Veszprem, Hungary, 8200

India, Gujrat

Ahemedabad - 4, Gujrat, India, 380009

India, Maharashtra

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

Chennai, Tamil Nadu, India, 600 006

Coimbatore, Tamil Nadu, India, 641014

Madurai, Tamil Nadu, India, 625 020

Pondicherry, Tamil Nadu, India, 600007

India

Bangalore, India, 560010

Chandigarh, India, 160012

Hyderabad, India, 500 034

Kerala, India, 683572

Kolkata, India, 700073

Mumbai, India, 400 050

New Delhi, India, 110002

New Delhi, India, 110029

Orissa, India, 751 024

Israel

Afula, Israel

Beer Sheva, Israel

Haifa, Israel, 34362

Jerusalem, Israel, 91120

Kfar Saba, Israel

Petach Tikva, Israel, 49100

Rehovot, Israel, 76100

Tel Aviv, Israel, 64239

Tel Hashomer, Israel

Zrifin, Israel, 70300

Italy

Ancona, Italy, 60126

Bari, Italy, 70124

Catania, Italy, 95123

Genova, Italy, 16132

Milano, Italy, 20122

Milano, Italy, 20132

Milano, Italy, 20157

Padova, Italy, 35128

Roma, Italy, 00133

Roma, Italy, 00168

Roma, Italy, 00198

Torino, Italy, 10122

Udine, Italy, 33100

Varese, Italy, 21100

Verona, Italy, 37121

Japan, Aichi

Nagoya, Aichi, Japan, 466-8560

Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

Kita, Kagawa, Japan, 761-0793

Japan, Osaka

Hirakata, Osaka, Japan, 573-1191

Suita, Osaka, Japan, 565-0871

Japan, Shiga

Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

Chiyoda-ku, Tokyo, Japan, 101-8309

Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

Fukuoka, Japan, 812-8582

Fukushima, Japan, 960-1295

Kagoshima, Japan, 890-8520

Kyoto, Japan, 606-8507

Korea, Republic of, Gyeonggido

Seongnam, Gyeonggido, Korea, Republic of, 463 707

Korea, Republic of

Incheon, Korea, Republic of, 405-760

Seoul, Korea, Republic of, 110 744

Seoul, Korea, Republic of, 137 701

Seoul, Korea, Republic of, 138-736

Seoul, Korea, Republic of, 152-703

Latvia

Riga, Latvia, 1002

Riga, Latvia, 1009

Riga, Latvia, 1050

Mexico, Distrito Federal

Mexico City, Distrito Federal, Mexico, 06800

Mexico, Jalisco

Zapopan, Jalisco, Mexico, 45060

Mexico, México

Metepec, México, Mexico, 52140

Mexico, Nuevo Leon

Monterrey, Nuevo Leon, Mexico, 64060

Monterrey, Nuevo Leon, Mexico, 64480

Mexico

Chihuahua, Mexico, 31238

Mexico City, Mexico, 06030

México D.F., Mexico, 04030

Netherlands, ZA

Leiden, ZA, Netherlands, 2333

Netherlands

Amsterdam, Netherlands, 1100 DD

Groningen, Netherlands, 9713 GZ

Nijmegen, Netherlands, 6525 EX

Rotterdam, Netherlands, 3000 CA

Poland

Bydgoszcz, Poland, 85-631

Gdansk, Poland, 80-952

Katowice, Poland, 40-760

Poznan, Poland, 61-848

Warszaa, Poland, 02-005

Warszawa, Poland, 00-416

Wroclaw, Poland, 50-368

Portugal

Coimbra, Portugal, 3000-548

Porto, Portugal, 4200-319

Singapore

Singapore, Singapore, 119074

Singapore, Singapore, 159964

Singapore, Singapore, 168751

Singapore, Singapore, 308433

Slovakia

Banska Bystrica, Slovakia, 97517

Bratislava, Slovakia, 81369

Spain, A Coruña

Santiago de Compostela, A Coruña, Spain, 15705

Spain, Asturias

Oviedo, Asturias, Spain, 33012

Spain, Navarra

Pamplona, Navarra, Spain, 31008

Spain

Alicante, Spain, 03016

Barcelona, Spain, 08017

Barcelona, Spain, 08022

Barcelona, Spain, 08035

Barcelona, Spain, 08036

Madrid, Spain, 28002

Madrid, Spain, 28046

Malaga, Spain, 29010

Sevilla, Spain, 41009

Sevilla, Spain, 41013

Valencia, Spain, 46014

Valencia, Spain, 46015

Valladolid, Spain, 47005

Sweden

Linköping, Sweden, 58185

Stockholm, Sweden, 11282

Örebro, Sweden, 70185

Switzerland

Basel, Switzerland, 4031

Bern, Switzerland, 3010

Genève, Switzerland, 1211

Zürich, Switzerland, 8091

United Kingdom, Hampshire

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Surrey

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

Aberdeen, United Kingdom, AB25 2ZN

Belfast, United Kingdom, BT12 6BA

Birmingham, United Kingdom, B4 7ET

Liverpool, United Kingdom, L7 8XP

London, United Kingdom, NW1 5QH

London, United Kingdom, SE5 9RS

Plymouth, United Kingdom, PL4 6PL

Torquay, United Kingdom, TQ2 7AA

IPDSharing

Plan to Share IPD:

References

Citations: **[Study Results]** Heier JS, Brown DM, Chong V, Korobelnik JF, Kaiser PK, Nguyen QD, Kirchhof B, Ho A, Ogura Y, Yancopoulos GD, Stahl N, Vitti R, Berliner AJ, Soo Y, Anderesi M, Groetzbach G, Sommerauer B, Sandbrink R, Simader C, Schmidt-Erfurth U; VIEW 1 and VIEW 2 Study Groups.

Intravitreal aflibercept (VEGF trap-eye) in wet age-related macular degeneration. Ophthalmology. 2012 Dec;119(12):2537-48. doi: 10.1016/j.ophtha.2012.09.006. Epub 2012 Oct 17. Erratum in: Ophthalmology. 2013 Jan;120(1):209-10. PubMed 23084240

[Study Results] Schmidt-Erfurth U, Kaiser PK, Korobelnik JF, Brown DM, Chong V, Nguyen QD, Ho AC, Ogura Y, Simader C, Jaffe GJ, Slakter JS, Yancopoulos GD, Stahl N, Vitti R, Berliner AJ, Soo Y, Anderesi M, Sowade O, Zeitz O, Norenberg C, Sandbrink R, Heier JS. Intravitreal aflibercept injection for neovascular age-related macular degeneration: ninety-six-week results of the VIEW studies. Ophthalmology. 2014 Jan;121(1):193-201. doi: 10.1016/j.ophtha.2013.08.011. Epub 2013 Sep 29. PubMed 24084500

Links: URL: http://clinicaltrials.gov/ct2/show/NCT00509795?term=NCT00509795;rank=1
Description: Click here to view the data of the twin trial conducted by the collaboration partner.

URL: http://www.clinicaltrialsregister.eu/
Description: Click here to find information about studies related to Bayer Healthcare products conducted in Europe

Available IPD/Information:

Study Results

Participant Flow

Recruitment Details	The study was conducted at 186 study centers in 26 countries. Recruitment period: 21 Apr 2008 - 4 Sep 2009.
Pre-assignment Details	2031 participants were screened, 1240 were randomized and 1204 received at least 1 dose of study drug. 1204 participants were included in the Safety-Analysis Set (SAS). 1202 participants with at least 1 post-baseline measurement were included in the Full-Analysis Set (FAS).

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Overall Study

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Started	303	313	311	313
Participants Received Treatment	291 [1]	309 [1]	297 [1]	307 [1]
Participants Treated (FAS)	291	309	296	306
Completed	276	281	274	284
Not Completed	27	32	37	29
Adverse Event	2	6	8	9
Death	1	3	2	1
Lack of Efficacy	0	0	1	1
Lost to Follow-up	4	1	2	2
Protocol Violation	2	1	1	0
Withdrawal by Subject	11	15	13	11
Other (no further information available)	7	6	10	5

[1] safety population

Baseline Characteristics

Reporting Groups

	Description

Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Baseline Measures

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Overall Number of Participants		291	309	296	306	1202
Age, Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		73.0 (9.0)	74.1 (8.5)	74.7 (8.6)	73.8 (8.6)	73.9 (8.7)
Sex: Female, Male [1]	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants

Measure type: Count of Participants Unit of measure: Participants		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
	Female	169 58.08%	176 56.96%	147 49.66%	175 57.19%	667 55.49%
	Male	122 41.92%	133 43.04%	149 50.34%	131 42.81%	535 44.51%
		[1] Measure Description: Information retrieved from all baseline participants.				
Ethnicity [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Not Hispanic or Latino		239 82.13%	259 83.82%	241 81.42%	251 82.03%	990 82.36%
Hispanic or Latino		52 17.87%	50 16.18%	55 18.58%	55 17.97%	212 17.64%
		[1] Measure Description: Information retrieved from all baseline participants.				
Race [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
White		213 73.2%	226 73.14%	219 73.99%	217 70.92%	875 72.8%
Black or African American		1 0.34%	0 0%	1 0.34%	2 0.65%	4 0.33%
Asian		60 20.62%	67 21.68%	61 20.61%	69 22.55%	257 21.38%
Missing		17 5.84%	16 5.18%	15 5.07%	18 5.88%	66 5.49%
		[1] Measure Description: Information retrieved from all baseline participants.				

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) total score [1]	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Mean (Standard Deviation) Unit of measure: scores on a scale		72.90 (19.09)	70.27 (19.41)	74.04 (18.22)	71.30 (19.06)	72.10 (18.99)
		[1] Measure Description: Information retrieved from 1201/1202 baseline participants. The possible range of the NEI VFQ-25 total score is between 0 (worst possible) and 100 (best possible).				
Area of Choroidal Neovascularization (CNV) [1]	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Mean (Standard Deviation) Unit of measure: mm^2		7.59 (5.34)	8.25 (5.77)	7.70 (5.26)	7.75 (5.52)	7.83 (5.48)
		[1] Measure Description: Information retrieved from 1200/1202 baseline participants.				
Baseline lesion type [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Predominantly classic		70 24.05%	72 23.3%	80 27.03%	88 28.76%	310 25.79%
Minimally classic		104 35.74%	112 36.25%	103 34.8%	106 34.64%	425 35.36%

Regeneron Ex. 2001
Fresenius v. Regeneron
IPR2025-01269
Page 2677 of 3000

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Occult		116 39.86%	123 39.81%	113 38.18%	110 35.95%	462 38.44%
Missing		1 0.34%	2 0.65%	0 0%	2 0.65%	5 0.42%
		[1] Measure Description: Information retrieved from 1197/1202 baseline participants.				
Baseline total lesion size [1] Mean (Standard Deviation) Unit of measure: mm^2	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		8.01 (5.74)	8.72 (6.14)	8.17 (5.51)	8.22 (5.87)	8.28 (5.82)
		[1] Measure Description: Information retrieved from 1198/1202 baseline participants.				
Best Corrected Visual Acuity (BCVA), assessed by ETDRS chart [1] Mean (Standard Deviation) Unit of measure: Letters correctly read	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		53.8 (13.5)	52.8 (13.9)	51.6 (14.2)	51.6 (13.9)	52.4 (13.9)
		[1] Measure Description: Information retrieved from all baseline participants. Only participants with a ETDRS (Early Treatment Diabetic Retinopathy Study) Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye at 4 meters were included; a higher score represents better functioning.				

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)
Measure Description	Maintenance of vision was defined as a loss of < 15 letters in the ETDRS (Early Treatment Diabetic Retinopathy Study) letter score (defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning. Nominator = (Number of participants who maintained vision * 100); Denominator = Number of participants analyzed.
Time Frame	At week 52

Analysis Population Description

Per-Protocol Set (PPS); imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	269	274	268	270
Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF) Measure Type: Number Unit of Measure: Percentage of participants	94.42	95.62	96.27	95.56

Statistical Analysis 1 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 2mg Q4, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 2mg Q4).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.20
	Confidence Interval	(2-sided) 95% -4.86 to 2.46
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 2mg Q4 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

Statistical Analysis 2 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 0.5mg Q4, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 0.5mg Q4).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.84
	Confidence Interval	(2-sided) 95% -5.40 to 1.71
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 0.5mg Q4 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

Statistical Analysis 3 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 2mg Q8, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 2mg Q8).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.13
	Confidence Interval	(2-sided) 95% -4.81 to 2.55
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 2mg Q8 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

2. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning.

Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set (FAS); imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	291	309	296	306
Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: Letters correctly read	9.4 (13.5)	7.6 (12.6)	9.7 (14.1)	8.9 (14.4)

Statistical Analysis 1 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.076
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.9484
	Confidence Interval	(2-sided) 95% -4.1009 to 0.2040
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.9555
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.0620
	Confidence Interval	(2-sided) 95% -2.2398 to 2.1158
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 0.5mg Q4

Statistical Analysis 3 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4131
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.9014
	Confidence Interval	(2-sided) 95% -3.0615 to 1.2587
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q8 group

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning. Nominator = (Number of participants who maintained vision * 100); Denominator = Number of participants analyzed.
Time Frame	At week 52

Analysis Population Description

Full-Analysis Set; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	291	309	296	306
Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF Measure Type: Number Unit of Measure: Percentage of participants	34.02	29.45	34.80	31.37

Statistical Analysis 1 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.229
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-4.57
	Confidence Interval	(2-sided) 95% -12.02 to 2.88
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q4 group

Statistical Analysis 2 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.843
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	0.78
	Confidence Interval	(2-sided) 95% -6.91 to 8.46
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 0.5mg Q4 group

Statistical Analysis 3 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.490
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-2.65
	Confidence Interval	(2-sided) 95% -10.18 to 4.88
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q8 group

4. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF
Measure Description	The possible range of the NEI VFQ-25 total score is between 0 (worst possible) and 100 (best possible).
Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set with assessment for this outcome measure; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	287	304	290	299
Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: Scores on a scale	6.3 (14.8)	4.5 (15.0)	5.1 (13.7)	4.9 (14.7)

Statistical Analysis 1 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0097
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-2.7885
	Confidence Interval	(2-sided) 95% -4.9012 to -0.6757
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3917
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.9320
	Confidence Interval	(2-sided) 95% -3.0658 to 1.2019
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 0.5mg Q4.

Statistical Analysis 3 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0717
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.9470
	Confidence Interval	(2-sided) 95% -4.0659 to 0.1718
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q8.

5. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF
Measure Description	CNV area values measured in square millimeters; lower values represent better outcomes.

Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set with assessment for this outcome measure; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	278	294	287	289
Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: mm^2	-4.16 (5.90)	-5.95 (6.12)	-4.24 (6.13)	-5.16 (5.87)

Statistical Analysis 1 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0038
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.180
	Confidence Interval	(2-sided) 95% -1.979 to -0.382
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.6784
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	0.170
	Confidence Interval	(2-sided) 95% -0.632 to 0.972
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 0.5mg Q4.

Statistical Analysis 3 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0727
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.733
	Confidence Interval	(2-sided) 95% -1.534 to 0.068
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 2mg Q8.

Reported Adverse Events

Time Frame	[Not specified]
Adverse Event Reporting Description	[Not specified]

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

All-Cause Mortality

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	/	/	/	/

Serious Adverse Events

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	65/291 (22.34%)	81/309 (26.21%)	72/297 (24.24%)	81/307 (26.38%)
Blood and lymphatic system disorders				
Anaemia [A*]	0/291 (0%)	2/309 (0.65%)	1/297 (0.34%)	0/307 (0%)
Febrile neutropenia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cardiac disorders				
Acute coronary syndrome [A*]	1/291 (0.34%)	2/309 (0.65%)	2/297 (0.67%)	2/307 (0.65%)
Acute myocardial infarction [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Angina pectoris [A*]	1/291 (0.34%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Angina unstable [A*]	1/291 (0.34%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Aortic valve stenosis [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Arrhythmia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Arteriosclerosis coronary artery [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Atrial fibrillation [A*]	2/291 (0.69%)	2/309 (0.65%)	2/297 (0.67%)	3/307 (0.98%)
Atrial flutter [A*]	0/291 (0%)	2/309 (0.65%)	1/297 (0.34%)	1/307 (0.33%)
Atrioventricular block [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bradycardia [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cardiac arrest [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cardiac disorder [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cardiac failure [A*]	1/291 (0.34%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Cardiac failure congestive [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Cardio-respiratory arrest [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cardiogenic shock [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cardiopulmonary failure [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cardiovascular insufficiency [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Coronary artery disease [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Coronary artery thrombosis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Left ventricular dysfunction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Mitral valve disease [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Mitral valve incompetence [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Myocardial infarction [A*]	4/291 (1.37%)	3/309 (0.97%)	3/297 (1.01%)	4/307 (1.3%)
Myocardial ischaemia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Palpitations [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Pericarditis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Sinus bradycardia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Supraventricular tachycardia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Ventricular arrhythmia [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Ventricular tachycardia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Ear and labyrinth disorders				
Tympanic membrane disorder [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Vertigo [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Eye disorders				
Age-related macular degeneration [A*]	0/291 (0%)	3/309 (0.97%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Blindness [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cataract [A*]	5/291 (1.72%)	4/309 (1.29%)	4/297 (1.35%)	4/307 (1.3%)
Cataract cortical [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cataract nuclear [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Cataract subcapsular [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Choroidal detachment [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Choroidal neovascularisation [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	2/307 (0.65%)
Hyphaema [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Iridocyclitis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Macular cyst [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Macular degeneration [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	3/307 (0.98%)
Macular hole [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Macular scar [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Maculopathy [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Ocular retrobulbar haemorrhage [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Posterior capsule opacification [A*]	2/291 (0.69%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Retinal degeneration [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Retinal detachment [A*]	3/291 (1.03%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Retinal haemorrhage [A*]	4/291 (1.37%)	3/309 (0.97%)	4/297 (1.35%)	2/307 (0.65%)
Retinal pigment epithelial tear [A*]	1/291 (0.34%)	0/309 (0%)	1/297 (0.34%)	2/307 (0.65%)
Retinal pigment epitheliopathy [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Retinal vein occlusion [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Visual acuity reduced [A*]	3/291 (1.03%)	5/309 (1.62%)	1/297 (0.34%)	7/307 (2.28%)
Vitreous detachment [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Vitreous haemorrhage [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Gastrointestinal disorders				
Abdominal mass [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Abdominal pain [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Abdominal pain upper [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Abnormal faeces [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Anal fistula [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bowel movement irregularity [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Colitis [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colonic polyp [A*]	2/291 (0.69%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Constipation [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Diverticulum [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Diverticulum intestinal [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Enterovesical fistula [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Femoral hernia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Femoral hernia, obstructive [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Gastric ulcer [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Gastritis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Gastritis erosive [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Inguinal hernia [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Intestinal obstruction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Large intestine perforation [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lower gastrointestinal haemorrhage [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nausea [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Pancreatitis [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Pancreatitis acute [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Rectal polyp [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Rectal prolapse [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Small intestinal obstruction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
General disorders				
Asthenia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Chest pain [A*]	3/291 (1.03%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Chills [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Death [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Device dislocation [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Device malfunction [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Disease progression [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Hernia [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Malaise [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Multi-organ failure [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Oedema peripheral [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Pyrexia [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	1/307 (0.33%)
Hepatobiliary disorders				
Bile duct stone [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cholecystitis [A*]	1/291 (0.34%)	2/309 (0.65%)	0/297 (0%)	0/307 (0%)
Cholecystitis acute [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cholelithiasis [A*]	0/291 (0%)	2/309 (0.65%)	2/297 (0.67%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Jaundice cholestatic [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Infections and infestations				
Appendicitis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Bronchitis [A*]	1/291 (0.34%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Diverticulitis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Dysentery [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Endophthalmitis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Escherichia sepsis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gastroenteritis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gastroenteritis norovirus [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Gastroenteritis salmonella [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Herpes zoster [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Herpes zoster ophthalmic [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Liver abscess [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Peridiverticular abscess [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Pneumonia [A*]	1/291 (0.34%)	4/309 (1.29%)	2/297 (0.67%)	6/307 (1.95%)
Pneumonia pneumococcal [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Postoperative wound infection [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Pyelonephritis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Respiratory tract infection [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Septic shock [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Urinary tract infection [A*]	2/291 (0.69%)	2/309 (0.65%)	1/297 (0.34%)	0/307 (0%)
Urosepsis [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Injury, poisoning and procedural complications				
Accident [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Ankle fracture [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Burns second degree [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cerebral haemorrhage traumatic [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Clavicle fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Concussion [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Contusion [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Eye injury [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Fall [A*]	2/291 (0.69%)	1/309 (0.32%)	1/297 (0.34%)	3/307 (0.98%)
Femoral neck fracture [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Femur fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Graft thrombosis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Head injury [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Hip fracture [A*]	2/291 (0.69%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Injury [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Jaw fracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Joint dislocation [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Joint injury [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Lower limb fracture [A*]	0/291 (0%)	0/309 (0%)	2/297 (0.67%)	0/307 (0%)
Lumbar vertebral fracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Meniscus lesion [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Patella fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Post procedural complication [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Radius fracture [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Rib fracture [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Road traffic accident [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Skull fractured base [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Spinal column injury [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Subdural haematoma [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Traumatic brain injury [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Traumatic haematoma [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Ulna fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Upper limb fracture [A*]	2/291 (0.69%)	1/309 (0.32%)	3/297 (1.01%)	0/307 (0%)
Wound haemorrhage [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Wrist fracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Investigations				
Blood osmolarity decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Electrocardiogram QT prolonged [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Haematocrit decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Haemoglobin decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Intraocular pressure increased [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	2/307 (0.65%)
Investigation [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Mean cell haemoglobin decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Mean cell volume decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Red blood cell count decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Metabolism and nutrition disorders				
Dehydration [A*]	2/291 (0.69%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Diabetes mellitus [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gout [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Hyperglycaemia [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hypokalaemia [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Hyponatraemia [A*]	0/291 (0%)	0/309 (0%)	2/297 (0.67%)	0/307 (0%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Arthritis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Back pain [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Dupuytren's contracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Foot deformity [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Intervertebral disc degeneration [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Intervertebral disc protrusion [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lumbar spinal stenosis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Neck pain [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Osteoarthritis [A*]	0/291 (0%)	0/309 (0%)	3/297 (1.01%)	1/307 (0.33%)
Rheumatoid arthritis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Rotator cuff syndrome [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Sjogren's syndrome [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Spinal column stenosis [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Synovitis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Acute myeloid leukaemia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Basal cell carcinoma [A*]	1/291 (0.34%)	0/309 (0%)	2/297 (0.67%)	0/307 (0%)
Benign salivary gland neoplasm [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Bladder cancer [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bladder cancer recurrent [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bladder cancer stage 0, with cancer in situ [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bladder neoplasm [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Breast cancer [A*]	1/291 (0.34%)	0/309 (0%)	3/297 (1.01%)	1/307 (0.33%)
Carcinoid tumour [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colon cancer [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colon cancer metastatic [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colon cancer recurrent [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Gastric cancer [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Glioblastoma multiforme [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lung cancer metastatic [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lung carcinoma cell type unspecified stage IV [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lung neoplasm malignant [A*]	0/291 (0%)	0/309 (0%)	2/297 (0.67%)	1/307 (0.33%)
Lymphoma [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Meningioma [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Metastases to bone [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Metastases to ovary [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Myelodysplastic syndrome [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Oesophageal carcinoma [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Ovarian cancer [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Pancreatic carcinoma [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Prostate cancer metastatic [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Squamous cell carcinoma [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Uterine leiomyoma [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nervous system disorders				
Brain oedema [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Cerebral infarction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cerebrovascular accident [A*]	2/291 (0.69%)	2/309 (0.65%)	1/297 (0.34%)	2/307 (0.65%)
Dementia Alzheimer's type [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Epilepsy [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Headache [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Hypertensive encephalopathy [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Ischaemic stroke [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lacunar infarction [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Lumbar radiculopathy [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nerve root compression [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Normal pressure hydrocephalus [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Petit mal epilepsy [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Presyncope [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Sciatica [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Subarachnoid haemorrhage [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Syncope [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Transient ischaemic attack [A*]	1/291 (0.34%)	2/309 (0.65%)	0/297 (0%)	0/307 (0%)
VIIth nerve paralysis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Psychiatric disorders				
Confusional state [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Depression [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Renal and urinary disorders				
Cystitis noninfective [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nephrolithiasis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Renal failure [A*]	0/291 (0%)	3/309 (0.97%)	0/297 (0%)	2/307 (0.65%)
Renal failure acute [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Urinary retention [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Urinary tract obstruction [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Reproductive system and breast disorders				
Benign prostatic hyperplasia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Ovarian cyst [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Uterine haemorrhage [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Vaginal prolapse [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Respiratory, thoracic and mediastinal disorders				
Acute pulmonary oedema [A*]	2/291 (0.69%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Asthma [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Chronic obstructive pulmonary disease [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Cough [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Dyspnoea [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Lung disorder [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Pleurisy [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Pneumothorax [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Pulmonary hypertension [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Respiratory tract congestion [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Sleep apnoea syndrome [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Skin and subcutaneous tissue disorders				
Dermal cyst [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Dermatitis allergic [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Erythema multiforme [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Pemphigus [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Rash [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	0/307 (0%)
Skin necrosis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Skin ulcer [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Urticaria [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Surgical and medical procedures				
Blepharoplasty [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Haematoma evacuation [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hip surgery [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Strangulated hernia repair [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Surgery [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Vaginal operation [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Vascular disorders				
Circulatory collapse [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Deep vein thrombosis [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Haematoma [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hypertension [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Hypertensive crisis [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	2/307 (0.65%)
Peripheral arterial occlusive disease [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Peripheral artery aneurysm [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Varicose vein [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Venous thrombosis limb A*	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA (14.0)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	254/291 (87.29%)	259/309 (83.82%)	251/297 (84.51%)	260/307 (84.69%)
Cardiac disorders				
Atrioventricular block first degree A*	16/291 (5.5%)	25/309 (8.09%)	23/297 (7.74%)	22/307 (7.17%)
Eye disorders				
Age-related macular degeneration A*	26/291 (8.93%)	28/309 (9.06%)	26/297 (8.75%)	38/307 (12.38%)
Cataract A*	29/291 (9.97%)	36/309 (11.65%)	34/297 (11.45%)	32/307 (10.42%)
Choroidal neovascularisation A*	28/291 (9.62%)	25/309 (8.09%)	28/297 (9.43%)	23/307 (7.49%)
Conjunctival haemorrhage A*	34/291 (11.68%)	33/309 (10.68%)	46/297 (15.49%)	35/307 (11.4%)
Conjunctival hyperaemia A*	18/291 (6.19%)	8/309 (2.59%)	11/297 (3.7%)	5/307 (1.63%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Conjunctivitis [A*]	19/291 (6.53%)	14/309 (4.53%)	8/297 (2.69%)	21/307 (6.84%)
Detachment of retinal pigment epithelium [A*]	38/291 (13.06%)	37/309 (11.97%)	33/297 (11.11%)	31/307 (10.1%)
Dry eye [A*]	14/291 (4.81%)	12/309 (3.88%)	15/297 (5.05%)	16/307 (5.21%)
Eye pain [A*]	28/291 (9.62%)	36/309 (11.65%)	25/297 (8.42%)	24/307 (7.82%)
Macular cyst [A*]	18/291 (6.19%)	8/309 (2.59%)	9/297 (3.03%)	9/307 (2.93%)
Macular degeneration [A*]	37/291 (12.71%)	35/309 (11.33%)	42/297 (14.14%)	51/307 (16.61%)
Macular oedema [A*]	17/291 (5.84%)	16/309 (5.18%)	23/297 (7.74%)	22/307 (7.17%)
Maculopathy [A*]	13/291 (4.47%)	16/309 (5.18%)	18/297 (6.06%)	10/307 (3.26%)
Ocular hyperaemia [A*]	20/291 (6.87%)	18/309 (5.83%)	17/297 (5.72%)	10/307 (3.26%)
Retinal cyst [A*]	13/291 (4.47%)	20/309 (6.47%)	17/297 (5.72%)	13/307 (4.23%)
Retinal degeneration [A*]	33/291 (11.34%)	37/309 (11.97%)	27/297 (9.09%)	23/307 (7.49%)
Retinal haemorrhage [A*]	82/291 (28.18%)	84/309 (27.18%)	70/297 (23.57%)	82/307 (26.71%)
Retinal oedema [A*]	34/291 (11.68%)	32/309 (10.36%)	31/297 (10.44%)	40/307 (13.03%)
Retinal pigment epitheliopathy [A*]	28/291 (9.62%)	23/309 (7.44%)	20/297 (6.73%)	28/307 (9.12%)
Visual acuity reduced [A*]	46/291 (15.81%)	44/309 (14.24%)	55/297 (18.52%)	60/307 (19.54%)
Vitreous detachment [A*]	22/291 (7.56%)	30/309 (9.71%)	17/297 (5.72%)	24/307 (7.82%)
Gastrointestinal disorders				

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Diarrhoea [A*]	14/291 (4.81%)	9/309 (2.91%)	16/297 (5.39%)	16/307 (5.21%)
General disorders				
Pyrexia [A*]	19/291 (6.53%)	12/309 (3.88%)	19/297 (6.4%)	8/307 (2.61%)
Infections and infestations				
Bronchitis [A*]	13/291 (4.47%)	17/309 (5.5%)	20/297 (6.73%)	12/307 (3.91%)
Influenza [A*]	14/291 (4.81%)	19/309 (6.15%)	12/297 (4.04%)	23/307 (7.49%)
Nasopharyngitis [A*]	39/291 (13.4%)	25/309 (8.09%)	32/297 (10.77%)	26/307 (8.47%)
Investigations				
Blood glucose increased [A*]	9/291 (3.09%)	17/309 (5.5%)	14/297 (4.71%)	18/307 (5.86%)
Intraocular pressure increased [A*]	37/291 (12.71%)	38/309 (12.3%)	24/297 (8.08%)	29/307 (9.45%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A*]	11/291 (3.78%)	8/309 (2.59%)	15/297 (5.05%)	7/307 (2.28%)
Back pain [A*]	17/291 (5.84%)	19/309 (6.15%)	12/297 (4.04%)	16/307 (5.21%)
Nervous system disorders				
Dizziness [A*]	15/291 (5.15%)	8/309 (2.59%)	4/297 (1.35%)	5/307 (1.63%)
Headache [A*]	14/291 (4.81%)	12/309 (3.88%)	16/297 (5.39%)	20/307 (6.51%)
Vascular disorders				
Hypertension [A*]	42/291 (14.43%)	41/309 (13.27%)	33/297 (11.11%)	34/307 (11.07%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA (14.0)

Limitations and Caveats

The conditional sequence of hypothesis testing had to stop after testing the first superiority hypothesis. Therefore, all further statistical tests are exploratory tests.

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Official Title: Therapeutic Area Head
Organization: BAYER
Phone:
Email: clinical-trials-contact@bayerhealthcare.com

Scroll up to access the controls Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes

Regeneron Ex. 2001
Fresenius v. Regeneron
IPR2025-01269
Page 2725 of 3000

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility

Version	A	B	Submitted Date	Changes
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	◉	◉	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: (•) Merged ( ) Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: April 25, 2014 (v29)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD)

Secondary IDs: 2007-000583-25 [EudraCT Number]

Study Status

Record Verification: April 2014

Overall Status: Completed

Study Start: April 2008

Primary Completion: September 2010 [Actual]

Study Completion: August 2011 [Actual]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Results First Submitted:	December 16, 2011
Results First Submitted that Met QC Criteria:	December 16, 2011
Results First Posted:	January 23, 2012 [Estimate]
Last Update Submitted that Met QC Criteria:	April 25, 2014
Last Update Posted:	May 8, 2014 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	Sponsor
Collaborators:	Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description: Data of this trial ("VIEW 2") was pooled with data of a sister trial ("VIEW 1", NCT00509795), and an integrated analyses of the combined data was performed.

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1240 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Active Comparator: Ranibizumab 0.5mg Q4 Participants received a 0.5 mg dose of Ranibizumab via intravitreal (IVT) injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Drug: Ranibizumab Participants received a 0.5 mg dose of Ranibizumab via intravitreal (IVT) injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4 Participants received a 2.0 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 2.0 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4 Participants received a 0.5 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 0.5 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8 Participants received a 2.0 mg dose of Aflibercept Injection administered every 8 weeks (including one additional 2,0 mg dose at Week 4) for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 2.0 mg dose of Aflibercept Injection administered every 8 weeks (including one additional 2,0 mg dose at Week 4) for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by Fluorescein angiography (FA) in the study eye.
- ETDRS Best-Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Ciudad Auton. de Buenos Aires**

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1015ABO

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1023AAQ

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1122AAI

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1181ACH

Argentina, Santa Fe

Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

Córdoba, Argentina, X5000IIT

Australia, New South Wales

Chatswood, New South Wales, Australia, 2067

Sydney, New South Wales, Australia, 2000

Westmead, New South Wales, Australia, 2145

Australia, Victoria

East Melbourne, Victoria, Australia, 3002

Parkville, Victoria, Australia, 3050

Australia, Western Australia

Nedlands, Western Australia, Australia, 6009

Australia

Parramatta, Australia, 2150

Austria

Innsbruck, Austria, 6020

Linz, Austria, 4021

Wien, Austria, 1090

Belgium

Liege, Belgium, 4000

Brazil, Sao Paulo

Ribeirão Preto, Sao Paulo, Brazil, 14048-900

São Paulo, Sao Paulo, Brazil, 05651-901

Brazil

Minas Gerais, Brazil, 30150-270

Sao Paulo, Brazil, 04023-062

Colombia, Antioquia

Medellín, Antioquia, Colombia

Colombia, Cauca

Cali, Cauca, Colombia

Colombia, Distrito Capital de Bogotá

Bogota, Distrito Capital de Bogotá, Colombia

Czech Republic

Brno, Czech Republic, 63400

Olomouc, Czech Republic, 77520

Praha 10, Czech Republic, 10034

Praha 4, Czech Republic, 14000

Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

Paris, Cedex 12, France, 75557

France, Cedex 1

Nantes, Cedex 1, France, 44093

France

Besancon, France, 25030

Bordeaux, France, 33000

Dijon, France, 21079

Lyon, France, 69003

Lyon, France, 69006

Marseille, France, 13008

Paris, France, 75010

Paris, France, 75015

Germany, Baden-Württemberg

Freiburg, Baden-Württemberg, Germany, 79106

Heidelberg, Baden-Württemberg, Germany, 69120

Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

München, Bayern, Germany, 81675

Regensburg, Bayern, Germany, 93053

Germany, Hessen

Darmstadt, Hessen, Germany, 64297

Germany, Nordrhein-Westfalen

Aachen, Nordrhein-Westfalen, Germany, 52074

Bonn, Nordrhein-Westfalen, Germany, 53105

Essen, Nordrhein-Westfalen, Germany, 45122

Köln, Nordrhein-Westfalen, Germany, 50924

Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

Ludwigshafen, Rheinland-Pfalz, Germany, 67063

Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

Homburg, Saarland, Germany, 66421

Germany, Sachsen

Dresden, Sachsen, Germany, 01307

Dresden, Sachsen, Germany, 06067

Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

Kiel, Schleswig-Holstein, Germany, 24105

Lübeck, Schleswig-Holstein, Germany, 23538

Germany

Berlin, Germany, 12200

Hamburg, Germany, 20251

Hungary

Budapest, Hungary, 1083

Budapest, Hungary, 1106

Budapest, Hungary, 1133

Veszprem, Hungary, 8200

India, Gujrat

Ahemedabad - 4, Gujrat, India, 380009

India, Maharashtra

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

Chennai, Tamil Nadu, India, 600 006

Coimbatore, Tamil Nadu, India, 641014

Madurai, Tamil Nadu, India, 625 020

Pondicherry, Tamil Nadu, India, 600007

India

Bangalore, India, 560010

Chandigarh, India, 160012

Hyderabad, India, 500 034

Kerala, India, 683572

Kolkata, India, 700073

Mumbai, India, 400 050

New Delhi, India, 110002

New Delhi, India, 110029

Orissa, India, 751 024

Israel

Afula, Israel

Beer Sheva, Israel

Haifa, Israel, 34362

Jerusalem, Israel, 91120

Kfar Saba, Israel

Petach Tikva, Israel, 49100

Rehovot, Israel, 76100

Tel Aviv, Israel, 64239

Tel Hashomer, Israel

Zrifin, Israel, 70300

Italy

Ancona, Italy, 60126

Bari, Italy, 70124

Catania, Italy, 95123

Genova, Italy, 16132

Milano, Italy, 20122

Milano, Italy, 20132

Milano, Italy, 20157

Padova, Italy, 35128

Roma, Italy, 00133

Roma, Italy, 00168

Roma, Italy, 00198

Torino, Italy, 10122

Udine, Italy, 33100

Varese, Italy, 21100

Verona, Italy, 37121

Japan, Aichi

Nagoya, Aichi, Japan, 466-8560

Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

Kita, Kagawa, Japan, 761-0793

Japan, Osaka

Hirakata, Osaka, Japan, 573-1191

Suita, Osaka, Japan, 565-0871

Japan, Shiga

Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

Chiyoda-ku, Tokyo, Japan, 101-8309

Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

Fukuoka, Japan, 812-8582

Fukushima, Japan, 960-1295

Kagoshima, Japan, 890-8520

Kyoto, Japan, 606-8507

Korea, Republic of, Gyeonggido

Seongnam, Gyeonggido, Korea, Republic of, 463 707

Korea, Republic of

Incheon, Korea, Republic of, 405-760

Seoul, Korea, Republic of, 110 744

Seoul, Korea, Republic of, 137 701

Seoul, Korea, Republic of, 138-736

Seoul, Korea, Republic of, 152-703

Latvia

Riga, Latvia, 1002

Riga, Latvia, 1009

Riga, Latvia, 1050

Regeneron Ex. 2001
Fresenius v. Regeneron
IPR2025-01269
Page 2741 of 3000

Mexico, Distrito Federal

Mexico City, Distrito Federal, Mexico, 06800

Mexico, Jalisco

Zapopan, Jalisco, Mexico, 45060

Mexico, México

Metepec, México, Mexico, 52140

Mexico, Nuevo Leon

Monterrey, Nuevo Leon, Mexico, 64060

Monterrey, Nuevo Leon, Mexico, 64480

Mexico

Chihuahua, Mexico, 31238

Mexico City, Mexico, 06030

México D.F., Mexico, 04030

Netherlands, ZA

Leiden, ZA, Netherlands, 2333

Netherlands

Amsterdam, Netherlands, 1100 DD

Groningen, Netherlands, 9713 GZ

Nijmegen, Netherlands, 6525 EX

Rotterdam, Netherlands, 3000 CA

Poland

Bydgoszcz, Poland, 85-631

Gdansk, Poland, 80-952

Katowice, Poland, 40-760

Poznan, Poland, 61-848

Warszaa, Poland, 02-005

Warszawa, Poland, 00-416

Wroclaw, Poland, 50-368

Portugal

Coimbra, Portugal, 3000-548

Porto, Portugal, 4200-319

Singapore

Singapore, Singapore, 119074

Singapore, Singapore, 159964

Singapore, Singapore, 168751

Singapore, Singapore, 308433

Slovakia

Banska Bystrica, Slovakia, 97517

Bratislava, Slovakia, 81369

Spain, A Coruña

Santiago de Compostela, A Coruña, Spain, 15705

Spain, Asturias

Oviedo, Asturias, Spain, 33012

Spain, Navarra

Pamplona, Navarra, Spain, 31008

Spain

Alicante, Spain, 03016

Barcelona, Spain, 08017

Barcelona, Spain, 08022

Barcelona, Spain, 08035

Barcelona, Spain, 08036

Madrid, Spain, 28002

Madrid, Spain, 28046

Malaga, Spain, 29010

Sevilla, Spain, 41009

Sevilla, Spain, 41013

Valencia, Spain, 46014

Valencia, Spain, 46015

Valladolid, Spain, 47005

Sweden

Linköping, Sweden, 58185

Stockholm, Sweden, 11282

Örebro, Sweden, 70185

Switzerland

Basel, Switzerland, 4031

Bern, Switzerland, 3010

Genève, Switzerland, 1211

Zürich, Switzerland, 8091

United Kingdom, Hampshire

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Surrey

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

Aberdeen, United Kingdom, AB25 2ZN

Belfast, United Kingdom, BT12 6BA

Birmingham, United Kingdom, B4 7ET

Liverpool, United Kingdom, L7 8XP

London, United Kingdom, NW1 5QH

London, United Kingdom, SE5 9RS

Plymouth, United Kingdom, PL4 6PL

Torquay, United Kingdom, TQ2 7AA

IPDSharing

Plan to Share IPD:

References

Citations: **[Study Results]** Heier JS, Brown DM, Chong V, Korobelnik JF, Kaiser PK, Nguyen QD, Kirchhof B, Ho A, Ogura Y, Yancopoulos GD, Stahl N, Vitti R, Berliner AJ, Soo Y, Anderesi M, Groetzbach G, Sommerauer B, Sandbrink R, Simader C, Schmidt-Erfurth U; VIEW 1 and VIEW 2 Study Groups.

Intravitreal aflibercept (VEGF trap-eye) in wet age-related macular degeneration. Ophthalmology. 2012 Dec;119(12):2537-48. doi: 10.1016/j.ophtha.2012.09.006. Epub 2012 Oct 17. Erratum in: Ophthalmology. 2013 Jan;120(1):209-10. PubMed 23084240

[Study Results] Schmidt-Erfurth U, Kaiser PK, Korobelnik JF, Brown DM, Chong V, Nguyen QD, Ho AC, Ogura Y, Simader C, Jaffe GJ, Slakter JS, Yancopoulos GD, Stahl N, Vitti R, Berliner AJ, Soo Y, Anderesi M, Sowade O, Zeitz O, Norenberg C, Sandbrink R, Heier JS. Intravitreal aflibercept injection for neovascular age-related macular degeneration: ninety-six-week results of the VIEW studies. Ophthalmology. 2014 Jan;121(1):193-201. doi: 10.1016/j.ophtha.2013.08.011. Epub 2013 Sep 29. PubMed 24084500

Links: URL: http://clinicaltrials.gov/ct2/show/NCT00509795?term=NCT00509795;rank=1
Description: Click here to view the data of the twin trial conducted by the collaboration partner.

Available IPD/Information:

Study Results

Participant Flow

Recruitment Details	The study was conducted at 186 study centers in 26 countries. Recruitment period: 21 Apr 2008 - 4 Sep 2009.
Pre-assignment Details	2031 participants were screened, 1240 were randomized and 1204 received at least 1 dose of study drug. 1204 participants were included in the Safety-Analysis Set (SAS). 1202 participants with at least 1 post-baseline measurement were included in the Full-Analysis Set (FAS).

Reporting Groups

	Description

Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Overall Study

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Started	303	313	311	313
Participants Received Treatment	291 [1]	309 [1]	297 [1]	307 [1]
Participants Treated (FAS)	291	309	296	306
Completed	276	281	274	284
Not Completed	27	32	37	29
Adverse Event	2	6	8	9
Death	1	3	2	1
Lack of Efficacy	0	0	1	1
Lost to Follow-up	4	1	2	2
Protocol Violation	2	1	1	0
Withdrawal by Subject	11	15	13	11
Other (no further information available)	7	6	10	5

[1] safety population

Baseline Characteristics

Reporting Groups

	Description

Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Baseline Measures

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Overall Number of Participants		291	309	296	306	1202
Age, Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		73.0 (9.0)	74.1 (8.5)	74.7 (8.6)	73.8 (8.6)	73.9 (8.7)
Sex: Female, Male [1]	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants

Measure type: Count of Participants Unit of measure: Participants		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
	Female	169 58.08%	176 56.96%	147 49.66%	175 57.19%	667 55.49%
	Male	122 41.92%	133 43.04%	149 50.34%	131 42.81%	535 44.51%
		[1] Measure Description: Information retrieved from all baseline participants.				
Ethnicity [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Not Hispanic or Latino		239 82.13%	259 83.82%	241 81.42%	251 82.03%	990 82.36%
Hispanic or Latino		52 17.87%	50 16.18%	55 18.58%	55 17.97%	212 17.64%
		[1] Measure Description: Information retrieved from all baseline participants.				
Race [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
White		213 73.2%	226 73.14%	219 73.99%	217 70.92%	875 72.8%
Black or African American		1 0.34%	0 0%	1 0.34%	2 0.65%	4 0.33%
Asian		60 20.62%	67 21.68%	61 20.61%	69 22.55%	257 21.38%
Missing		17 5.84%	16 5.18%	15 5.07%	18 5.88%	66 5.49%
		[1] Measure Description: Information retrieved from all baseline participants.				

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) total score [1]	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Mean (Standard Deviation) Unit of measure: scores on a scale		72.90 (19.09)	70.27 (19.41)	74.04 (18.22)	71.30 (19.06)	72.10 (18.99)
		[1] Measure Description: Information retrieved from 1201/1202 baseline participants. The possible range of the NEI VFQ-25 total score is between 0 (worst possible) and 100 (best possible).				
Area of Choroidal Neovascularization (CNV) [1]	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Mean (Standard Deviation) Unit of measure: mm^2		7.59 (5.34)	8.25 (5.77)	7.70 (5.26)	7.75 (5.52)	7.83 (5.48)
		[1] Measure Description: Information retrieved from 1200/1202 baseline participants.				
Baseline lesion type [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Predominantly classic		70 24.05%	72 23.3%	80 27.03%	88 28.76%	310 25.79%
Minimally classic		104 35.74%	112 36.25%	103 34.8%	106 34.64%	425 35.36%

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Occult		116 39.86%	123 39.81%	113 38.18%	110 35.95%	462 38.44%
Missing		1 0.34%	2 0.65%	0 0%	2 0.65%	5 0.42%
		[1] Measure Description: Information retrieved from 1197/1202 baseline participants.				
Baseline total lesion size [1] Mean (Standard Deviation) Unit of measure: mm^2	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		8.01 (5.74)	8.72 (6.14)	8.17 (5.51)	8.22 (5.87)	8.28 (5.82)
		[1] Measure Description: Information retrieved from 1198/1202 baseline participants.				
Best Corrected Visual Acuity (BCVA), assessed by ETDRS chart [1] Mean (Standard Deviation) Unit of measure: Letters correctly read	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		53.8 (13.5)	52.8 (13.9)	51.6 (14.2)	51.6 (13.9)	52.4 (13.9)
		[1] Measure Description: Information retrieved from all baseline participants. Only participants with a ETDRS (Early Treatment Diabetic Retinopathy Study) Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye at 4 meters were included; a higher score represents better functioning.				

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)
Measure Description	Maintenance of vision was defined as a loss of < 15 letters in the ETDRS (Early Treatment Diabetic Retinopathy Study) letter score (defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning. Nominator = (Number of participants who maintained vision * 100); Denominator = Number of participants analyzed.
Time Frame	At week 52

Analysis Population Description

Per-Protocol Set (PPS); imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	269	274	268	270
Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF) Measure Type: Number Unit of Measure: Percentage of participants	94.42	95.62	96.27	95.56

Statistical Analysis 1 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 2mg Q4, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 2mg Q4).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.20
	Confidence Interval	(2-sided) 95% -4.86 to 2.46
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 2mg Q4 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

Statistical Analysis 2 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 0.5mg Q4, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 0.5mg Q4).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.84
	Confidence Interval	(2-sided) 95% -5.40 to 1.71
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 0.5mg Q4 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

Statistical Analysis 3 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 2mg Q8, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 2mg Q8).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.13
	Confidence Interval	(2-sided) 95% -4.81 to 2.55
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 2mg Q8 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

2. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning.

Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set (FAS); imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	291	309	296	306
Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: Letters correctly read	9.4 (13.5)	7.6 (12.6)	9.7 (14.1)	8.9 (14.4)

Statistical Analysis 1 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.076
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.9484
	Confidence Interval	(2-sided) 95% -4.1009 to 0.2040
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.9555
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.0620
	Confidence Interval	(2-sided) 95% -2.2398 to 2.1158
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 0.5mg Q4

Statistical Analysis 3 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4131
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.9014
	Confidence Interval	(2-sided) 95% -3.0615 to 1.2587
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q8 group

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning. Nominator = (Number of participants who maintained vision * 100); Denominator = Number of participants analyzed.
Time Frame	At week 52

Analysis Population Description

Full-Analysis Set; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	291	309	296	306
Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF Measure Type: Number Unit of Measure: Percentage of participants	34.02	29.45	34.80	31.37

Statistical Analysis 1 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.229
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-4.57
	Confidence Interval	(2-sided) 95% -12.02 to 2.88
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q4 group

Statistical Analysis 2 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.843
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	0.78
	Confidence Interval	(2-sided) 95% -6.91 to 8.46
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 0.5mg Q4 group

Statistical Analysis 3 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.490
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-2.65
	Confidence Interval	(2-sided) 95% -10.18 to 4.88
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q8 group

4. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF
Measure Description	The possible range of the NEI VFQ-25 total score is between 0 (worst possible) and 100 (best possible).
Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set with assessment for this outcome measure; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	287	304	290	299
Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: Scores on a scale	6.3 (14.8)	4.5 (15.0)	5.1 (13.7)	4.9 (14.7)

Statistical Analysis 1 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0097
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-2.7885
	Confidence Interval	(2-sided) 95% -4.9012 to -0.6757
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3917
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.9320
	Confidence Interval	(2-sided) 95% -3.0658 to 1.2019
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 0.5mg Q4.

Statistical Analysis 3 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0717
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.9470
	Confidence Interval	(2-sided) 95% -4.0659 to 0.1718
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q8.

5. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF
Measure Description	CNV area values measured in square millimeters; lower values represent better outcomes.

Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set with assessment for this outcome measure; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	278	294	287	289
Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: mm^2	-4.16 (5.90)	-5.95 (6.12)	-4.24 (6.13)	-5.16 (5.87)

Statistical Analysis 1 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0038
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.180
	Confidence Interval	(2-sided) 95% -1.979 to -0.382
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.6784
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	0.170
	Confidence Interval	(2-sided) 95% -0.632 to 0.972
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 0.5mg Q4.

Statistical Analysis 3 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0727
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.733
	Confidence Interval	(2-sided) 95% -1.534 to 0.068
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 2mg Q8.

Reported Adverse Events

Time Frame	[Not specified]
Adverse Event Reporting Description	[Not specified]

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

All-Cause Mortality

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	/	/	/	/

Serious Adverse Events

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	65/291 (22.34%)	81/309 (26.21%)	72/297 (24.24%)	81/307 (26.38%)
Blood and lymphatic system disorders				
Anaemia [A*]	0/291 (0%)	2/309 (0.65%)	1/297 (0.34%)	0/307 (0%)
Febrile neutropenia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cardiac disorders				
Acute coronary syndrome [A*]	1/291 (0.34%)	2/309 (0.65%)	2/297 (0.67%)	2/307 (0.65%)
Acute myocardial infarction [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Angina pectoris [A*]	1/291 (0.34%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Angina unstable [A*]	1/291 (0.34%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Aortic valve stenosis [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Arrhythmia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Arteriosclerosis coronary artery [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Atrial fibrillation [A*]	2/291 (0.69%)	2/309 (0.65%)	2/297 (0.67%)	3/307 (0.98%)
Atrial flutter [A*]	0/291 (0%)	2/309 (0.65%)	1/297 (0.34%)	1/307 (0.33%)
Atrioventricular block [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bradycardia [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cardiac arrest [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cardiac disorder [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cardiac failure [A*]	1/291 (0.34%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Cardiac failure congestive [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Cardio-respiratory arrest [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cardiogenic shock [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cardiopulmonary failure [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cardiovascular insufficiency [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Coronary artery disease [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Coronary artery thrombosis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Left ventricular dysfunction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Mitral valve disease [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Mitral valve incompetence [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Myocardial infarction [A*]	4/291 (1.37%)	3/309 (0.97%)	3/297 (1.01%)	4/307 (1.3%)
Myocardial ischaemia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Palpitations [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Pericarditis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Sinus bradycardia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Supraventricular tachycardia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Ventricular arrhythmia [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Ventricular tachycardia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Ear and labyrinth disorders				
Tympanic membrane disorder [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Vertigo [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Eye disorders				
Age-related macular degeneration [A*]	0/291 (0%)	3/309 (0.97%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Blindness [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cataract [A*]	5/291 (1.72%)	4/309 (1.29%)	4/297 (1.35%)	4/307 (1.3%)
Cataract cortical [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cataract nuclear [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Cataract subcapsular [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Choroidal detachment [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Choroidal neovascularisation [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	2/307 (0.65%)
Hyphaema [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Iridocyclitis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Macular cyst [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Macular degeneration [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	3/307 (0.98%)
Macular hole [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Macular scar [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Maculopathy [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Ocular retrobulbar haemorrhage [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Posterior capsule opacification [A*]	2/291 (0.69%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Retinal degeneration [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Retinal detachment [A*]	3/291 (1.03%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Retinal haemorrhage [A*]	4/291 (1.37%)	3/309 (0.97%)	4/297 (1.35%)	2/307 (0.65%)
Retinal pigment epithelial tear [A*]	1/291 (0.34%)	0/309 (0%)	1/297 (0.34%)	2/307 (0.65%)
Retinal pigment epitheliopathy [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Retinal vein occlusion [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Visual acuity reduced [A*]	3/291 (1.03%)	5/309 (1.62%)	1/297 (0.34%)	7/307 (2.28%)
Vitreous detachment [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Vitreous haemorrhage [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Gastrointestinal disorders				
Abdominal mass [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Abdominal pain [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Abdominal pain upper [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Abnormal faeces [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Anal fistula [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bowel movement irregularity [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Colitis [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colonic polyp [A*]	2/291 (0.69%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Constipation [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Diverticulum [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Diverticulum intestinal [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Enterovesical fistula [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Femoral hernia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Femoral hernia, obstructive [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Gastric ulcer [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Gastritis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Gastritis erosive [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Inguinal hernia [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Intestinal obstruction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Large intestine perforation [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lower gastrointestinal haemorrhage [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nausea [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Pancreatitis [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Pancreatitis acute [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Rectal polyp [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Rectal prolapse [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Small intestinal obstruction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
General disorders				
Asthenia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Chest pain [A*]	3/291 (1.03%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Chills [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Death [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Device dislocation [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Device malfunction [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Disease progression [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Hernia [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Malaise [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Multi-organ failure [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Oedema peripheral [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Pyrexia [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	1/307 (0.33%)
Hepatobiliary disorders				
Bile duct stone [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cholecystitis [A*]	1/291 (0.34%)	2/309 (0.65%)	0/297 (0%)	0/307 (0%)
Cholecystitis acute [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cholelithiasis [A*]	0/291 (0%)	2/309 (0.65%)	2/297 (0.67%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Jaundice cholestatic [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Infections and infestations				
Appendicitis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Bronchitis [A*]	1/291 (0.34%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Diverticulitis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Dysentery [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Endophthalmitis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Escherichia sepsis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gastroenteritis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gastroenteritis norovirus [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Gastroenteritis salmonella [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Herpes zoster [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Herpes zoster ophthalmic [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Liver abscess [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Peridiverticular abscess [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Pneumonia [A*]	1/291 (0.34%)	4/309 (1.29%)	2/297 (0.67%)	6/307 (1.95%)
Pneumonia pneumococcal [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Postoperative wound infection [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Pyelonephritis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Respiratory tract infection [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Septic shock [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Urinary tract infection [A*]	2/291 (0.69%)	2/309 (0.65%)	1/297 (0.34%)	0/307 (0%)
Urosepsis [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Injury, poisoning and procedural complications				
Accident [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Ankle fracture [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Burns second degree [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cerebral haemorrhage traumatic [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Clavicle fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Concussion [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Contusion [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Eye injury [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Fall [A*]	2/291 (0.69%)	1/309 (0.32%)	1/297 (0.34%)	3/307 (0.98%)
Femoral neck fracture [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Femur fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Graft thrombosis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Head injury [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Hip fracture [A*]	2/291 (0.69%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Injury [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Jaw fracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Joint dislocation [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Joint injury [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Lower limb fracture [A*]	0/291 (0%)	0/309 (0%)	2/297 (0.67%)	0/307 (0%)
Lumbar vertebral fracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Meniscus lesion [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Patella fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Post procedural complication [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Radius fracture [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Rib fracture [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Road traffic accident [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Skull fractured base [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Spinal column injury [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Subdural haematoma [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Traumatic brain injury [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Traumatic haematoma [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Ulna fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Upper limb fracture [A*]	2/291 (0.69%)	1/309 (0.32%)	3/297 (1.01%)	0/307 (0%)
Wound haemorrhage [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Wrist fracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Investigations				
Blood osmolarity decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Electrocardiogram QT prolonged [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Haematocrit decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Haemoglobin decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Intraocular pressure increased [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	2/307 (0.65%)
Investigation [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Mean cell haemoglobin decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Mean cell volume decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Red blood cell count decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Metabolism and nutrition disorders				
Dehydration [A*]	2/291 (0.69%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Diabetes mellitus [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gout [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Hyperglycaemia [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hypokalaemia [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Hyponatraemia [A*]	0/291 (0%)	0/309 (0%)	2/297 (0.67%)	0/307 (0%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Arthritis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Back pain [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Dupuytren's contracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Foot deformity [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Intervertebral disc degeneration [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Intervertebral disc protrusion [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lumbar spinal stenosis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Neck pain [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Osteoarthritis [A*]	0/291 (0%)	0/309 (0%)	3/297 (1.01%)	1/307 (0.33%)
Rheumatoid arthritis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Rotator cuff syndrome [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Sjogren's syndrome [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Spinal column stenosis [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Synovitis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Acute myeloid leukaemia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Basal cell carcinoma [A*]	1/291 (0.34%)	0/309 (0%)	2/297 (0.67%)	0/307 (0%)
Benign salivary gland neoplasm [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Bladder cancer [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bladder cancer recurrent [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bladder cancer stage 0, with cancer in situ [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bladder neoplasm [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Breast cancer [A*]	1/291 (0.34%)	0/309 (0%)	3/297 (1.01%)	1/307 (0.33%)
Carcinoid tumour [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colon cancer [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colon cancer metastatic [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colon cancer recurrent [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Gastric cancer [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Glioblastoma multiforme [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lung cancer metastatic [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lung carcinoma cell type unspecified stage IV [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lung neoplasm malignant [A*]	0/291 (0%)	0/309 (0%)	2/297 (0.67%)	1/307 (0.33%)
Lymphoma [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Meningioma [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Metastases to bone [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Metastases to ovary [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Myelodysplastic syndrome [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Oesophageal carcinoma [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Ovarian cancer [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Pancreatic carcinoma [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Prostate cancer metastatic [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Squamous cell carcinoma [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Uterine leiomyoma [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nervous system disorders				
Brain oedema [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Cerebral infarction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cerebrovascular accident [A*]	2/291 (0.69%)	2/309 (0.65%)	1/297 (0.34%)	2/307 (0.65%)
Dementia Alzheimer's type [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Epilepsy [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Headache [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Hypertensive encephalopathy [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Ischaemic stroke [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lacunar infarction [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Lumbar radiculopathy [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nerve root compression [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Normal pressure hydrocephalus [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Petit mal epilepsy [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Presyncope [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Sciatica [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Subarachnoid haemorrhage [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Syncope [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Transient ischaemic attack [A*]	1/291 (0.34%)	2/309 (0.65%)	0/297 (0%)	0/307 (0%)
VIIth nerve paralysis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Psychiatric disorders				
Confusional state [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Depression [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Renal and urinary disorders				
Cystitis noninfective [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nephrolithiasis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Renal failure [A*]	0/291 (0%)	3/309 (0.97%)	0/297 (0%)	2/307 (0.65%)
Renal failure acute [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Urinary retention [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Urinary tract obstruction [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Reproductive system and breast disorders				
Benign prostatic hyperplasia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Ovarian cyst [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Uterine haemorrhage [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Vaginal prolapse [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Respiratory, thoracic and mediastinal disorders				
Acute pulmonary oedema [A*]	2/291 (0.69%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Asthma [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Chronic obstructive pulmonary disease [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Cough [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Dyspnoea [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Lung disorder [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Pleurisy [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Pneumothorax [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Pulmonary hypertension [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Respiratory tract congestion [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Sleep apnoea syndrome [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Skin and subcutaneous tissue disorders				
Dermal cyst [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Dermatitis allergic [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Erythema multiforme [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Pemphigus [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Rash [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	0/307 (0%)
Skin necrosis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Skin ulcer [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Urticaria [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Surgical and medical procedures				
Blepharoplasty [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Haematoma evacuation [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hip surgery [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Strangulated hernia repair [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Surgery [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Vaginal operation [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Vascular disorders				
Circulatory collapse [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Deep vein thrombosis [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Haematoma [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hypertension [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Hypertensive crisis [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	2/307 (0.65%)
Peripheral arterial occlusive disease [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Peripheral artery aneurysm [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Varicose vein [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Venous thrombosis limb A*	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA (14.0)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	254/291 (87.29%)	259/309 (83.82%)	251/297 (84.51%)	260/307 (84.69%)
Cardiac disorders				
Atrioventricular block first degree A*	16/291 (5.5%)	25/309 (8.09%)	23/297 (7.74%)	22/307 (7.17%)
Eye disorders				
Age-related macular degeneration A*	26/291 (8.93%)	28/309 (9.06%)	26/297 (8.75%)	38/307 (12.38%)
Cataract A*	29/291 (9.97%)	36/309 (11.65%)	34/297 (11.45%)	32/307 (10.42%)
Choroidal neovascularisation A*	28/291 (9.62%)	25/309 (8.09%)	28/297 (9.43%)	23/307 (7.49%)
Conjunctival haemorrhage A*	34/291 (11.68%)	33/309 (10.68%)	46/297 (15.49%)	35/307 (11.4%)
Conjunctival hyperaemia A*	18/291 (6.19%)	8/309 (2.59%)	11/297 (3.7%)	5/307 (1.63%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Conjunctivitis [A*]	19/291 (6.53%)	14/309 (4.53%)	8/297 (2.69%)	21/307 (6.84%)
Detachment of retinal pigment epithelium [A*]	38/291 (13.06%)	37/309 (11.97%)	33/297 (11.11%)	31/307 (10.1%)
Dry eye [A*]	14/291 (4.81%)	12/309 (3.88%)	15/297 (5.05%)	16/307 (5.21%)
Eye pain [A*]	28/291 (9.62%)	36/309 (11.65%)	25/297 (8.42%)	24/307 (7.82%)
Macular cyst [A*]	18/291 (6.19%)	8/309 (2.59%)	9/297 (3.03%)	9/307 (2.93%)
Macular degeneration [A*]	37/291 (12.71%)	35/309 (11.33%)	42/297 (14.14%)	51/307 (16.61%)
Macular oedema [A*]	17/291 (5.84%)	16/309 (5.18%)	23/297 (7.74%)	22/307 (7.17%)
Maculopathy [A*]	13/291 (4.47%)	16/309 (5.18%)	18/297 (6.06%)	10/307 (3.26%)
Ocular hyperaemia [A*]	20/291 (6.87%)	18/309 (5.83%)	17/297 (5.72%)	10/307 (3.26%)
Retinal cyst [A*]	13/291 (4.47%)	20/309 (6.47%)	17/297 (5.72%)	13/307 (4.23%)
Retinal degeneration [A*]	33/291 (11.34%)	37/309 (11.97%)	27/297 (9.09%)	23/307 (7.49%)
Retinal haemorrhage [A*]	82/291 (28.18%)	84/309 (27.18%)	70/297 (23.57%)	82/307 (26.71%)
Retinal oedema [A*]	34/291 (11.68%)	32/309 (10.36%)	31/297 (10.44%)	40/307 (13.03%)
Retinal pigment epitheliopathy [A*]	28/291 (9.62%)	23/309 (7.44%)	20/297 (6.73%)	28/307 (9.12%)
Visual acuity reduced [A*]	46/291 (15.81%)	44/309 (14.24%)	55/297 (18.52%)	60/307 (19.54%)
Vitreous detachment [A*]	22/291 (7.56%)	30/309 (9.71%)	17/297 (5.72%)	24/307 (7.82%)
Gastrointestinal disorders				

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Diarrhoea [A*]	14/291 (4.81%)	9/309 (2.91%)	16/297 (5.39%)	16/307 (5.21%)
General disorders				
Pyrexia [A*]	19/291 (6.53%)	12/309 (3.88%)	19/297 (6.4%)	8/307 (2.61%)
Infections and infestations				
Bronchitis [A*]	13/291 (4.47%)	17/309 (5.5%)	20/297 (6.73%)	12/307 (3.91%)
Influenza [A*]	14/291 (4.81%)	19/309 (6.15%)	12/297 (4.04%)	23/307 (7.49%)
Nasopharyngitis [A*]	39/291 (13.4%)	25/309 (8.09%)	32/297 (10.77%)	26/307 (8.47%)
Investigations				
Blood glucose increased [A*]	9/291 (3.09%)	17/309 (5.5%)	14/297 (4.71%)	18/307 (5.86%)
Intraocular pressure increased [A*]	37/291 (12.71%)	38/309 (12.3%)	24/297 (8.08%)	29/307 (9.45%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A*]	11/291 (3.78%)	8/309 (2.59%)	15/297 (5.05%)	7/307 (2.28%)
Back pain [A*]	17/291 (5.84%)	19/309 (6.15%)	12/297 (4.04%)	16/307 (5.21%)
Nervous system disorders				
Dizziness [A*]	15/291 (5.15%)	8/309 (2.59%)	4/297 (1.35%)	5/307 (1.63%)
Headache [A*]	14/291 (4.81%)	12/309 (3.88%)	16/297 (5.39%)	20/307 (6.51%)
Vascular disorders				
Hypertension [A*]	42/291 (14.43%)	41/309 (13.27%)	33/297 (11.11%)	34/307 (11.07%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA (14.0)

Limitations and Caveats

The conditional sequence of hypothesis testing had to stop after testing the first superiority hypothesis. Therefore, all further statistical tests are exploratory tests.

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Official Title: Therapeutic Area Head
Organization: BAYER
Phone:
Email: clinical-trials-contact@bayerhealthcare.com

Scroll up to access the controls Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes

Regeneron Ex. 2001
Fresenius v. Regeneron
IPR2025-01269
Page 2799 of 3000

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility

Version	A	B	Submitted Date	Changes
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	○	○	February 27, 2012	Study Status and More Information
28	◉	◉	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: (•) Merged ( ) Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: March 12, 2013 (v28)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD)

Secondary IDs: 2007-000583-25 [EudraCT Number]

Study Status

Record Verification: March 2013

Overall Status: Completed

Study Start: April 2008

Primary Completion: September 2010 [Actual]

Study Completion: August 2011 [Actual]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Results First Submitted:	December 16, 2011
Results First Submitted that Met QC Criteria:	December 16, 2011
Results First Posted:	January 23, 2012 [Estimate]
Last Update Submitted that Met QC Criteria:	March 12, 2013
Last Update Posted:	March 15, 2013 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	
Collaborators:	Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description: Data of this trial ("VIEW 2") was pooled with data of a sister trial ("VIEW 1", NCT00509795), and an integrated analyses of the combined data was performed.

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1240 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Active Comparator: Ranibizumab 0.5mg Q4 Participants received a 0.5 mg dose of Ranibizumab via intravitreal (IVT) injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Drug: Ranibizumab Participants received a 0.5 mg dose of Ranibizumab via intravitreal (IVT) injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4 Participants received a 2.0 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 2.0 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4 Participants received a 0.5 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 0.5 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8 Participants received a 2.0 mg dose of Aflibercept Injection administered every 8 weeks (including one additional 2,0 mg dose at Week 4) for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 2.0 mg dose of Aflibercept Injection administered every 8 weeks (including one additional 2,0 mg dose at Week 4) for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by Fluorescein angiography (FA) in the study eye.
- ETDRS Best-Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Ciudad Auton. de Buenos Aires**

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1015ABO

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1023AAQ

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1122AAI

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1181ACH

Argentina, Santa Fe

Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

Córdoba, Argentina, X5000IIT

Australia, New South Wales

Chatswood, New South Wales, Australia, 2067

Sydney, New South Wales, Australia, 2000

Westmead, New South Wales, Australia, 2145

Australia, Victoria

East Melbourne, Victoria, Australia, 3002

Parkville, Victoria, Australia, 3050

Australia, Western Australia

Nedlands, Western Australia, Australia, 6009

Australia

Parramatta, Australia, 2150

Austria

Innsbruck, Austria, 6020

Linz, Austria, 4021

Wien, Austria, 1090

Belgium

Liege, Belgium, 4000

Brazil, Sao Paulo

Ribeirão Preto, Sao Paulo, Brazil, 14048-900

São Paulo, Sao Paulo, Brazil, 05651-901

Brazil

Minas Gerais, Brazil, 30150-270

Sao Paulo, Brazil, 04023-062

Colombia, Antioquia

Medellín, Antioquia, Colombia

Colombia, Cauca

Cali, Cauca, Colombia

Colombia, Distrito Capital de Bogotá

Bogota, Distrito Capital de Bogotá, Colombia

Czech Republic

Brno, Czech Republic, 63400

Olomouc, Czech Republic, 77520

Praha 10, Czech Republic, 10034

Praha 4, Czech Republic, 14000

Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

Paris, Cedex 12, France, 75557

France, Cedex 1

Nantes, Cedex 1, France, 44093

France

Besancon, France, 25030

Bordeaux, France, 33000

Dijon, France, 21079

Lyon, France, 69003

Lyon, France, 69006

Marseille, France, 13008

Paris, France, 75010

Paris, France, 75015

Germany, Baden-Württemberg

Freiburg, Baden-Württemberg, Germany, 79106

Heidelberg, Baden-Württemberg, Germany, 69120

Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

München, Bayern, Germany, 81675

Regensburg, Bayern, Germany, 93053

Germany, Hessen

Darmstadt, Hessen, Germany, 64297

Germany, Nordrhein-Westfalen

Aachen, Nordrhein-Westfalen, Germany, 52074

Bonn, Nordrhein-Westfalen, Germany, 53105

Essen, Nordrhein-Westfalen, Germany, 45122

Köln, Nordrhein-Westfalen, Germany, 50924

Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

Ludwigshafen, Rheinland-Pfalz, Germany, 67063

Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

Homburg, Saarland, Germany, 66421

Germany, Sachsen

Dresden, Sachsen, Germany, 01307

Dresden, Sachsen, Germany, 06067

Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

Kiel, Schleswig-Holstein, Germany, 24105

Lübeck, Schleswig-Holstein, Germany, 23538

Germany

Berlin, Germany, 12200

Hamburg, Germany, 20251

Hungary

Budapest, Hungary, 1083

Budapest, Hungary, 1106

Budapest, Hungary, 1133

Veszprem, Hungary, 8200

India, Gujrat

Ahemedabad - 4, Gujrat, India, 380009

India, Maharashtra

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

Chennai, Tamil Nadu, India, 600 006

Coimbatore, Tamil Nadu, India, 641014

Madurai, Tamil Nadu, India, 625 020

Pondicherry, Tamil Nadu, India, 600007

India

Bangalore, India, 560010

Chandigarh, India, 160012

Hyderabad, India, 500 034

Kerala, India, 683572

Kolkata, India, 700073

Mumbai, India, 400 050

New Delhi, India, 110002

New Delhi, India, 110029

Orissa, India, 751 024

Israel

Afula, Israel

Beer Sheva, Israel

Haifa, Israel, 34362

Jerusalem, Israel, 91120

Kfar Saba, Israel

Petach Tikva, Israel, 49100

Rehovot, Israel, 76100

Tel Aviv, Israel, 64239

Tel Hashomer, Israel

Zrifin, Israel, 70300

Italy

Ancona, Italy, 60126

Bari, Italy, 70124

Catania, Italy, 95123

Genova, Italy, 16132

Milano, Italy, 20122

Milano, Italy, 20132

Milano, Italy, 20157

Padova, Italy, 35128

Roma, Italy, 00133

Roma, Italy, 00168

Roma, Italy, 00198

Torino, Italy, 10122

Udine, Italy, 33100

Varese, Italy, 21100

Verona, Italy, 37121

Japan, Aichi

Nagoya, Aichi, Japan, 466-8560

Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

Kita, Kagawa, Japan, 761-0793

Japan, Osaka

Hirakata, Osaka, Japan, 573-1191

Suita, Osaka, Japan, 565-0871

Japan, Shiga

Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

Chiyoda-ku, Tokyo, Japan, 101-8309

Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

Fukuoka, Japan, 812-8582

Fukushima, Japan, 960-1295

Kagoshima, Japan, 890-8520

Kyoto, Japan, 606-8507

Korea, Republic of, Gyeonggido

Seongnam, Gyeonggido, Korea, Republic of, 463 707

Korea, Republic of

Incheon, Korea, Republic of, 405-760

Seoul, Korea, Republic of, 110 744

Seoul, Korea, Republic of, 137 701

Seoul, Korea, Republic of, 138-736

Seoul, Korea, Republic of, 152-703

Latvia

Riga, Latvia, 1002

Riga, Latvia, 1009

Riga, Latvia, 1050

Mexico, Distrito Federal

Mexico City, Distrito Federal, Mexico, 06800

Mexico, Jalisco

Zapopan, Jalisco, Mexico, 45060

Mexico, México

Metepec, México, Mexico, 52140

Mexico, Nuevo Leon

Monterrey, Nuevo Leon, Mexico, 64060

Monterrey, Nuevo Leon, Mexico, 64480

Mexico

Chihuahua, Mexico, 31238

Mexico City, Mexico, 06030

México D.F., Mexico, 04030

Netherlands, ZA

Leiden, ZA, Netherlands, 2333

Netherlands

Amsterdam, Netherlands, 1100 DD

Groningen, Netherlands, 9713 GZ

Nijmegen, Netherlands, 6525 EX

Rotterdam, Netherlands, 3000 CA

Poland

Bydgoszcz, Poland, 85-631

Gdansk, Poland, 80-952

Katowice, Poland, 40-760

Poznan, Poland, 61-848

Warszaa, Poland, 02-005

Warszawa, Poland, 00-416

Wroclaw, Poland, 50-368

Portugal

Coimbra, Portugal, 3000-548

Porto, Portugal, 4200-319

Singapore

Singapore, Singapore, 119074

Singapore, Singapore, 159964

Singapore, Singapore, 168751

Singapore, Singapore, 308433

Slovakia

Banska Bystrica, Slovakia, 97517

Bratislava, Slovakia, 81369

Spain, A Coruña

Santiago de Compostela, A Coruña, Spain, 15705

Spain, Asturias

Oviedo, Asturias, Spain, 33012

Spain, Navarra

Pamplona, Navarra, Spain, 31008

Spain

Alicante, Spain, 03016

Barcelona, Spain, 08017

Barcelona, Spain, 08022

Barcelona, Spain, 08035

Barcelona, Spain, 08036

Madrid, Spain, 28002

Madrid, Spain, 28046

Malaga, Spain, 29010

Sevilla, Spain, 41009

Sevilla, Spain, 41013

Valencia, Spain, 46014

Valencia, Spain, 46015

Valladolid, Spain, 47005

Sweden

Linköping, Sweden, 58185

Stockholm, Sweden, 11282

Örebro, Sweden, 70185

Switzerland

Basel, Switzerland, 4031

Bern, Switzerland, 3010

Genève, Switzerland, 1211

Zürich, Switzerland, 8091

United Kingdom, Hampshire

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Surrey

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

Aberdeen, United Kingdom, AB25 2ZN

Belfast, United Kingdom, BT12 6BA

Birmingham, United Kingdom, B4 7ET

Liverpool, United Kingdom, L7 8XP

London, United Kingdom, NW1 5QH

London, United Kingdom, SE5 9RS

Plymouth, United Kingdom, PL4 6PL

Torquay, United Kingdom, TQ2 7AA

IPDSharing

Plan to Share IPD:

References

Citations: **[Study Results]** Heier JS, Brown DM, Chong V, Korobelnik JF, Kaiser PK, Nguyen QD, Kirchhof B, Ho A, Ogura Y, Yancopoulos GD, Stahl N, Vitti R, Berliner AJ, Soo Y, Anderesi M, Groetzbach G, Sommerauer B, Sandbrink R, Simader C, Schmidt-Erfurth U; VIEW 1 and VIEW 2 Study Groups.

Intravitreal aflibercept (VEGF trap-eye) in wet age-related macular degeneration. Ophthalmology. 2012 Dec;119(12):2537-48. doi: 10.1016/j.ophtha.2012.09.006. Epub 2012 Oct 17. Erratum in: Ophthalmology. 2013 Jan;120(1):209-10. PubMed 23084240

Links: URL: http://clinicaltrials.gov/ct2/show/NCT00509795?term=NCT00509795;rank=1
Description: Click here to view the data of the twin trial conducted by the collaboration partner.

Available IPD/Information:

Study Results

Participant Flow

Recruitment Details	The study was conducted at 186 study centers in 26 countries. Recruitment period: 21 Apr 2008 - 4 Sep 2009.
Pre-assignment Details	2031 participants were screened, 1240 were randomized and 1204 received at least 1 dose of study drug. 1204 participants were included in the Safety-Analysis Set (SAS). 1202 participants with at least 1 post-baseline measurement were included in the Full-Analysis Set (FAS).

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Overall Study

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Started	303	313	311	313
Participants Received Treatment	291 [1]	309 [1]	297 [1]	307 [1]
Participants Treated (FAS)	291	309	296	306
Completed	276	281	274	284
Not Completed	27	32	37	29
Adverse Event	2	6	8	9
Death	1	3	2	1
Lack of Efficacy	0	0	1	1
Lost to Follow-up	4	1	2	2
Protocol Violation	2	1	1	0
Withdrawal by Subject	11	15	13	11
Other (no further information available)	7	6	10	5

[1] safety population

Baseline Characteristics

Reporting Groups

	Description

Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Baseline Measures

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Overall Number of Participants		291	309	296	306	1202
Age Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		73.0 (9.0)	74.1 (8.5)	74.7 (8.6)	73.8 (8.6)	73.9 (8.7)
Sex: Female, Male [1]	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants

Measure type: Count of Participants Unit of measure: Participants		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
	Female	169 58.08%	176 56.96%	147 49.66%	175 57.19%	667 55.49%
	Male	122 41.92%	133 43.04%	149 50.34%	131 42.81%	535 44.51%
		[1] Measure Description: Information retrieved from all baseline participants.				
Ethnicity [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Not Hispanic or Latino		239 82.13%	259 83.82%	241 81.42%	251 82.03%	990 82.36%
Hispanic or Latino		52 17.87%	50 16.18%	55 18.58%	55 17.97%	212 17.64%
		[1] Measure Description: Information retrieved from all baseline participants.				
Race [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
White		213 73.2%	226 73.14%	219 73.99%	217 70.92%	875 72.8%
Black or African American		1 0.34%	0 0%	1 0.34%	2 0.65%	4 0.33%
Asian		60 20.62%	67 21.68%	61 20.61%	69 22.55%	257 21.38%
Missing		17 5.84%	16 5.18%	15 5.07%	18 5.88%	66 5.49%
		[1] Measure Description: Information retrieved from all baseline participants.				

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) total score [1]	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Mean (Standard Deviation) Unit of measure: scores on a scale		72.90 (19.09)	70.27 (19.41)	74.04 (18.22)	71.30 (19.06)	72.10 (18.99)
		[1] Measure Description: Information retrieved from 1201/1202 baseline participants. The possible range of the NEI VFQ-25 total score is between 0 (worst possible) and 100 (best possible).				
Area of Choroidal Neovascularization (CNV) [1]	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Mean (Standard Deviation) Unit of measure: mm^2		7.59 (5.34)	8.25 (5.77)	7.70 (5.26)	7.75 (5.52)	7.83 (5.48)
		[1] Measure Description: Information retrieved from 1200/1202 baseline participants.				
Baseline lesion type [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Predominantly classic		70 24.05%	72 23.3%	80 27.03%	88 28.76%	310 25.79%
Minimally classic		104 35.74%	112 36.25%	103 34.8%	106 34.64%	425 35.36%

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Occult		116 39.86%	123 39.81%	113 38.18%	110 35.95%	462 38.44%
Missing		1 0.34%	2 0.65%	0 0%	2 0.65%	5 0.42%
		[1] Measure Description: Information retrieved from 1197/1202 baseline participants.				
Baseline total lesion size [1] Mean (Standard Deviation) Unit of measure: mm^2	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		8.01 (5.74)	8.72 (6.14)	8.17 (5.51)	8.22 (5.87)	8.28 (5.82)
		[1] Measure Description: Information retrieved from 1198/1202 baseline participants.				
Best Corrected Visual Acuity (BCVA), assessed by ETDRS chart [1] Mean (Standard Deviation) Unit of measure: Letters correctly read	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		53.8 (13.5)	52.8 (13.9)	51.6 (14.2)	51.6 (13.9)	52.4 (13.9)
		[1] Measure Description: Information retrieved from all baseline participants. Only participants with a ETDRS (Early Treatment Diabetic Retinopathy Study) Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye at 4 meters were included; a higher score represents better functioning.				

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)
Measure Description	Maintenance of vision was defined as a loss of < 15 letters in the ETDRS (Early Treatment Diabetic Retinopathy Study) letter score (defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning. Nominator = (Number of participants who maintained vision * 100); Denominator = Number of participants analyzed.
Time Frame	At week 52

Analysis Population Description

Per-Protocol Set (PPS); imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	269	274	268	270
Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF) Measure Type: Number Unit of Measure: Percentage of participants	94.42	95.62	96.27	95.56

Statistical Analysis 1 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 2mg Q4, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 2mg Q4).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.20
	Confidence Interval	(2-sided) 95% -4.86 to 2.46
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 2mg Q4 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

Statistical Analysis 2 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 0.5mg Q4, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 0.5mg Q4).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.84
	Confidence Interval	(2-sided) 95% -5.40 to 1.71
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 0.5mg Q4 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

Statistical Analysis 3 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 2mg Q8, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 2mg Q8).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.13
	Confidence Interval	(2-sided) 95% -4.81 to 2.55
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 2mg Q8 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

2. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning.

Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set (FAS); imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	291	309	296	306
Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: Letters correctly read	9.4 (13.5)	7.6 (12.6)	9.7 (14.1)	8.9 (14.4)

Statistical Analysis 1 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.076
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.9484
	Confidence Interval	(2-sided) 95% -4.1009 to 0.2040
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.9555
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.0620
	Confidence Interval	(2-sided) 95% -2.2398 to 2.1158
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 0.5mg Q4

Statistical Analysis 3 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4131
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.9014
	Confidence Interval	(2-sided) 95% -3.0615 to 1.2587
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q8 group

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning. Nominator = (Number of participants who maintained vision * 100); Denominator = Number of participants analyzed.
Time Frame	At week 52

Analysis Population Description

Full-Analysis Set; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	291	309	296	306
Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF Measure Type: Number Unit of Measure: Percentage of participants	34.02	29.45	34.80	31.37

Statistical Analysis 1 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.229
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-4.57
	Confidence Interval	(2-sided) 95% -12.02 to 2.88
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q4 group

Statistical Analysis 2 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.843
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	0.78
	Confidence Interval	(2-sided) 95% -6.91 to 8.46
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 0.5mg Q4 group

Statistical Analysis 3 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.490
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-2.65
	Confidence Interval	(2-sided) 95% -10.18 to 4.88
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q8 group

4. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF
Measure Description	The possible range of the NEI VFQ-25 total score is between 0 (worst possible) and 100 (best possible).
Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set with assessment for this outcome measure; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	287	304	290	299
Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: Scores on a scale	6.3 (14.8)	4.5 (15.0)	5.1 (13.7)	4.9 (14.7)

Statistical Analysis 1 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0097
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-2.7885
	Confidence Interval	(2-sided) 95% -4.9012 to -0.6757
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3917
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.9320
	Confidence Interval	(2-sided) 95% -3.0658 to 1.2019
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 0.5mg Q4.

Statistical Analysis 3 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0717
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.9470
	Confidence Interval	(2-sided) 95% -4.0659 to 0.1718
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q8.

5. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF
Measure Description	CNV area values measured in square millimeters; lower values represent better outcomes.

Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set with assessment for this outcome measure; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	278	294	287	289
Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: mm^2	-4.16 (5.90)	-5.95 (6.12)	-4.24 (6.13)	-5.16 (5.87)

Statistical Analysis 1 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0038
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.180
	Confidence Interval	(2-sided) 95% -1.979 to -0.382
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.6784
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	0.170
	Confidence Interval	(2-sided) 95% -0.632 to 0.972
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 0.5mg Q4.

Statistical Analysis 3 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0727
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.733
	Confidence Interval	(2-sided) 95% -1.534 to 0.068
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 2mg Q8.

Reported Adverse Events

Time Frame	[Not specified]
Adverse Event Reporting Description	[Not specified]

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

All-Cause Mortality

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	/	/	/	/

Serious Adverse Events

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	65/291 (22.34%)	81/309 (26.21%)	72/297 (24.24%)	81/307 (26.38%)
Blood and lymphatic system disorders				
Anaemia [A*]	0/291 (0%)	2/309 (0.65%)	1/297 (0.34%)	0/307 (0%)
Febrile neutropenia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cardiac disorders				
Acute coronary syndrome [A*]	1/291 (0.34%)	2/309 (0.65%)	2/297 (0.67%)	2/307 (0.65%)
Acute myocardial infarction [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Angina pectoris [A*]	1/291 (0.34%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Angina unstable [A*]	1/291 (0.34%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Aortic valve stenosis [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Arrhythmia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Arteriosclerosis coronary artery [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Atrial fibrillation [A*]	2/291 (0.69%)	2/309 (0.65%)	2/297 (0.67%)	3/307 (0.98%)
Atrial flutter [A*]	0/291 (0%)	2/309 (0.65%)	1/297 (0.34%)	1/307 (0.33%)
Atrioventricular block [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bradycardia [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cardiac arrest [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cardiac disorder [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cardiac failure [A*]	1/291 (0.34%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Cardiac failure congestive [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Cardio-respiratory arrest [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cardiogenic shock [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cardiopulmonary failure [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cardiovascular insufficiency [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Coronary artery disease [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Coronary artery thrombosis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Left ventricular dysfunction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Mitral valve disease [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Mitral valve incompetence [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Myocardial infarction [A*]	4/291 (1.37%)	3/309 (0.97%)	3/297 (1.01%)	4/307 (1.3%)
Myocardial ischaemia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Palpitations [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Pericarditis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Sinus bradycardia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Supraventricular tachycardia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Ventricular arrhythmia [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Ventricular tachycardia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Ear and labyrinth disorders				
Tympanic membrane disorder [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Vertigo [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Eye disorders				
Age-related macular degeneration [A*]	0/291 (0%)	3/309 (0.97%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Blindness [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cataract [A*]	5/291 (1.72%)	4/309 (1.29%)	4/297 (1.35%)	4/307 (1.3%)
Cataract cortical [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cataract nuclear [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Cataract subcapsular [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Choroidal detachment [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Choroidal neovascularisation [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	2/307 (0.65%)
Hyphaema [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Iridocyclitis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Macular cyst [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Macular degeneration [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	3/307 (0.98%)
Macular hole [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Macular scar [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Maculopathy [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Ocular retrobulbar haemorrhage [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Posterior capsule opacification [A*]	2/291 (0.69%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Retinal degeneration [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Retinal detachment [A*]	3/291 (1.03%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Retinal haemorrhage [A*]	4/291 (1.37%)	3/309 (0.97%)	4/297 (1.35%)	2/307 (0.65%)
Retinal pigment epithelial tear [A*]	1/291 (0.34%)	0/309 (0%)	1/297 (0.34%)	2/307 (0.65%)
Retinal pigment epitheliopathy [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Retinal vein occlusion [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Visual acuity reduced [A*]	3/291 (1.03%)	5/309 (1.62%)	1/297 (0.34%)	7/307 (2.28%)
Vitreous detachment [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Vitreous haemorrhage [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Gastrointestinal disorders				
Abdominal mass [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Abdominal pain [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Abdominal pain upper [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Abnormal faeces [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Anal fistula [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bowel movement irregularity [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Colitis [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colonic polyp [A*]	2/291 (0.69%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Constipation [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Diverticulum [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Diverticulum intestinal [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Enterovesical fistula [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Femoral hernia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Femoral hernia, obstructive [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Gastric ulcer [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Gastritis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Gastritis erosive [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Inguinal hernia [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Intestinal obstruction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Large intestine perforation [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lower gastrointestinal haemorrhage [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nausea [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Pancreatitis [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Pancreatitis acute [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Rectal polyp [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Rectal prolapse [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Small intestinal obstruction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
General disorders				
Asthenia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Chest pain [A*]	3/291 (1.03%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Chills [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Death [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Device dislocation [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Device malfunction [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Disease progression [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Hernia [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Malaise [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Multi-organ failure [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Oedema peripheral [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Pyrexia [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	1/307 (0.33%)
Hepatobiliary disorders				
Bile duct stone [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cholecystitis [A*]	1/291 (0.34%)	2/309 (0.65%)	0/297 (0%)	0/307 (0%)
Cholecystitis acute [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cholelithiasis [A*]	0/291 (0%)	2/309 (0.65%)	2/297 (0.67%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Jaundice cholestatic [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Infections and infestations				
Appendicitis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Bronchitis [A*]	1/291 (0.34%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Diverticulitis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Dysentery [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Endophthalmitis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Escherichia sepsis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gastroenteritis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gastroenteritis norovirus [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Gastroenteritis salmonella [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Herpes zoster [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Herpes zoster ophthalmic [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Liver abscess [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Peridiverticular abscess [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Pneumonia [A*]	1/291 (0.34%)	4/309 (1.29%)	2/297 (0.67%)	6/307 (1.95%)
Pneumonia pneumococcal [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Postoperative wound infection [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Pyelonephritis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Respiratory tract infection [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Septic shock [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Urinary tract infection [A*]	2/291 (0.69%)	2/309 (0.65%)	1/297 (0.34%)	0/307 (0%)
Urosepsis [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Injury, poisoning and procedural complications				
Accident [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Ankle fracture [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Burns second degree [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cerebral haemorrhage traumatic [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Clavicle fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Concussion [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Contusion [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Eye injury [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Fall [A*]	2/291 (0.69%)	1/309 (0.32%)	1/297 (0.34%)	3/307 (0.98%)
Femoral neck fracture [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Femur fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Graft thrombosis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Head injury [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Hip fracture [A*]	2/291 (0.69%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Injury [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Jaw fracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Joint dislocation [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Joint injury [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Lower limb fracture [A*]	0/291 (0%)	0/309 (0%)	2/297 (0.67%)	0/307 (0%)
Lumbar vertebral fracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Meniscus lesion [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Patella fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Post procedural complication [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Radius fracture [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Rib fracture [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Road traffic accident [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Skull fractured base [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Spinal column injury [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Subdural haematoma [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Traumatic brain injury [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Traumatic haematoma [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Ulna fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Upper limb fracture [A*]	2/291 (0.69%)	1/309 (0.32%)	3/297 (1.01%)	0/307 (0%)
Wound haemorrhage [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Wrist fracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Investigations				
Blood osmolarity decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Electrocardiogram QT prolonged [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Haematocrit decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Haemoglobin decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Intraocular pressure increased [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	2/307 (0.65%)
Investigation [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Mean cell haemoglobin decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Mean cell volume decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Red blood cell count decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Metabolism and nutrition disorders				
Dehydration [A*]	2/291 (0.69%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Diabetes mellitus [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gout [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Hyperglycaemia [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hypokalaemia [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Hyponatraemia [A*]	0/291 (0%)	0/309 (0%)	2/297 (0.67%)	0/307 (0%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Arthritis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Back pain [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Dupuytren's contracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Foot deformity [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Intervertebral disc degeneration [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Intervertebral disc protrusion [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lumbar spinal stenosis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Neck pain [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Osteoarthritis [A*]	0/291 (0%)	0/309 (0%)	3/297 (1.01%)	1/307 (0.33%)
Rheumatoid arthritis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Rotator cuff syndrome [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Sjogren's syndrome [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Spinal column stenosis [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Synovitis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Acute myeloid leukaemia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Basal cell carcinoma [A*]	1/291 (0.34%)	0/309 (0%)	2/297 (0.67%)	0/307 (0%)
Benign salivary gland neoplasm [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Bladder cancer [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bladder cancer recurrent [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bladder cancer stage 0, with cancer in situ [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bladder neoplasm [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Breast cancer [A*]	1/291 (0.34%)	0/309 (0%)	3/297 (1.01%)	1/307 (0.33%)
Carcinoid tumour [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colon cancer [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colon cancer metastatic [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colon cancer recurrent [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Gastric cancer [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Glioblastoma multiforme [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lung cancer metastatic [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lung carcinoma cell type unspecified stage IV [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lung neoplasm malignant [A*]	0/291 (0%)	0/309 (0%)	2/297 (0.67%)	1/307 (0.33%)
Lymphoma [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Meningioma [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Metastases to bone [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Metastases to ovary [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Myelodysplastic syndrome [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Oesophageal carcinoma [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Ovarian cancer [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Pancreatic carcinoma [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Prostate cancer metastatic [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Squamous cell carcinoma [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Uterine leiomyoma [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nervous system disorders				
Brain oedema [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Cerebral infarction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cerebrovascular accident [A*]	2/291 (0.69%)	2/309 (0.65%)	1/297 (0.34%)	2/307 (0.65%)
Dementia Alzheimer's type [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Epilepsy [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Headache [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Hypertensive encephalopathy [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Ischaemic stroke [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lacunar infarction [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Lumbar radiculopathy [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nerve root compression [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Normal pressure hydrocephalus [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Petit mal epilepsy [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Presyncope [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Sciatica [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Subarachnoid haemorrhage [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Syncope [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Transient ischaemic attack [A*]	1/291 (0.34%)	2/309 (0.65%)	0/297 (0%)	0/307 (0%)
VIIth nerve paralysis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Psychiatric disorders				
Confusional state [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Depression [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Renal and urinary disorders				
Cystitis noninfective [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nephrolithiasis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Renal failure [A*]	0/291 (0%)	3/309 (0.97%)	0/297 (0%)	2/307 (0.65%)
Renal failure acute [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Urinary retention [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Urinary tract obstruction [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Reproductive system and breast disorders				
Benign prostatic hyperplasia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Ovarian cyst [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Uterine haemorrhage [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Vaginal prolapse [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Respiratory, thoracic and mediastinal disorders				
Acute pulmonary oedema [A*]	2/291 (0.69%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Asthma [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Chronic obstructive pulmonary disease [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Cough [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Dyspnoea [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Lung disorder [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Pleurisy [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Pneumothorax [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Pulmonary hypertension [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Respiratory tract congestion [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Sleep apnoea syndrome [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Skin and subcutaneous tissue disorders				
Dermal cyst [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Dermatitis allergic [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Erythema multiforme [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Pemphigus [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Rash [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	0/307 (0%)
Skin necrosis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Skin ulcer [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Urticaria [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Surgical and medical procedures				
Blepharoplasty [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Haematoma evacuation [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hip surgery [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Strangulated hernia repair [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Surgery [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Vaginal operation [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Vascular disorders				
Circulatory collapse [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Deep vein thrombosis [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Haematoma [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hypertension [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Hypertensive crisis [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	2/307 (0.65%)
Peripheral arterial occlusive disease [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Peripheral artery aneurysm [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Varicose vein [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Venous thrombosis limb A*	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA (14.0)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	254/291 (87.29%)	259/309 (83.82%)	251/297 (84.51%)	260/307 (84.69%)
Cardiac disorders				
Atrioventricular block first degree A*	16/291 (5.5%)	25/309 (8.09%)	23/297 (7.74%)	22/307 (7.17%)
Eye disorders				
Age-related macular degeneration A*	26/291 (8.93%)	28/309 (9.06%)	26/297 (8.75%)	38/307 (12.38%)
Cataract A*	29/291 (9.97%)	36/309 (11.65%)	34/297 (11.45%)	32/307 (10.42%)
Choroidal neovascularisation A*	28/291 (9.62%)	25/309 (8.09%)	28/297 (9.43%)	23/307 (7.49%)
Conjunctival haemorrhage A*	34/291 (11.68%)	33/309 (10.68%)	46/297 (15.49%)	35/307 (11.4%)
Conjunctival hyperaemia A*	18/291 (6.19%)	8/309 (2.59%)	11/297 (3.7%)	5/307 (1.63%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Conjunctivitis [A*]	19/291 (6.53%)	14/309 (4.53%)	8/297 (2.69%)	21/307 (6.84%)
Detachment of retinal pigment epithelium [A*]	38/291 (13.06%)	37/309 (11.97%)	33/297 (11.11%)	31/307 (10.1%)
Dry eye [A*]	14/291 (4.81%)	12/309 (3.88%)	15/297 (5.05%)	16/307 (5.21%)
Eye pain [A*]	28/291 (9.62%)	36/309 (11.65%)	25/297 (8.42%)	24/307 (7.82%)
Macular cyst [A*]	18/291 (6.19%)	8/309 (2.59%)	9/297 (3.03%)	9/307 (2.93%)
Macular degeneration [A*]	37/291 (12.71%)	35/309 (11.33%)	42/297 (14.14%)	51/307 (16.61%)
Macular oedema [A*]	17/291 (5.84%)	16/309 (5.18%)	23/297 (7.74%)	22/307 (7.17%)
Maculopathy [A*]	13/291 (4.47%)	16/309 (5.18%)	18/297 (6.06%)	10/307 (3.26%)
Ocular hyperaemia [A*]	20/291 (6.87%)	18/309 (5.83%)	17/297 (5.72%)	10/307 (3.26%)
Retinal cyst [A*]	13/291 (4.47%)	20/309 (6.47%)	17/297 (5.72%)	13/307 (4.23%)
Retinal degeneration [A*]	33/291 (11.34%)	37/309 (11.97%)	27/297 (9.09%)	23/307 (7.49%)
Retinal haemorrhage [A*]	82/291 (28.18%)	84/309 (27.18%)	70/297 (23.57%)	82/307 (26.71%)
Retinal oedema [A*]	34/291 (11.68%)	32/309 (10.36%)	31/297 (10.44%)	40/307 (13.03%)
Retinal pigment epitheliopathy [A*]	28/291 (9.62%)	23/309 (7.44%)	20/297 (6.73%)	28/307 (9.12%)
Visual acuity reduced [A*]	46/291 (15.81%)	44/309 (14.24%)	55/297 (18.52%)	60/307 (19.54%)
Vitreous detachment [A*]	22/291 (7.56%)	30/309 (9.71%)	17/297 (5.72%)	24/307 (7.82%)
Gastrointestinal disorders				

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Diarrhoea [A*]	14/291 (4.81%)	9/309 (2.91%)	16/297 (5.39%)	16/307 (5.21%)
General disorders				
Pyrexia [A*]	19/291 (6.53%)	12/309 (3.88%)	19/297 (6.4%)	8/307 (2.61%)
Infections and infestations				
Bronchitis [A*]	13/291 (4.47%)	17/309 (5.5%)	20/297 (6.73%)	12/307 (3.91%)
Influenza [A*]	14/291 (4.81%)	19/309 (6.15%)	12/297 (4.04%)	23/307 (7.49%)
Nasopharyngitis [A*]	39/291 (13.4%)	25/309 (8.09%)	32/297 (10.77%)	26/307 (8.47%)
Investigations				
Blood glucose increased [A*]	9/291 (3.09%)	17/309 (5.5%)	14/297 (4.71%)	18/307 (5.86%)
Intraocular pressure increased [A*]	37/291 (12.71%)	38/309 (12.3%)	24/297 (8.08%)	29/307 (9.45%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A*]	11/291 (3.78%)	8/309 (2.59%)	15/297 (5.05%)	7/307 (2.28%)
Back pain [A*]	17/291 (5.84%)	19/309 (6.15%)	12/297 (4.04%)	16/307 (5.21%)
Nervous system disorders				
Dizziness [A*]	15/291 (5.15%)	8/309 (2.59%)	4/297 (1.35%)	5/307 (1.63%)
Headache [A*]	14/291 (4.81%)	12/309 (3.88%)	16/297 (5.39%)	20/307 (6.51%)
Vascular disorders				
Hypertension [A*]	42/291 (14.43%)	41/309 (13.27%)	33/297 (11.11%)	34/307 (11.07%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA (14.0)

Limitations and Caveats

The conditional sequence of hypothesis testing had to stop after testing the first superiority hypothesis. Therefore, all further statistical tests are exploratory tests.

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Official Title: Therapeutic Area Head
Organization: BAYER
Phone:
Email: clinical-trials-contact@bayerhealthcare.com

Scroll up to access the controls Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00637377

Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Latest version (submitted November 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes

Regeneron Ex. 2001
Fresenius v. Regeneron
IPR2025-01269
Page 2873 of 3000

Version	A	B	Submitted Date	Changes
1	○	○	March 17, 2008	None (earliest Version on record)
2	○	○	April 24, 2008	Recruitment Status, Contacts/Locations, Study Status and Oversight
3	○	○	June 19, 2008	Contacts/Locations and Study Status
4	○	○	August 4, 2008	Contacts/Locations, Study Status and Eligibility
5	○	○	September 30, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators, Eligibility and Study Identification
6	○	○	October 2, 2008	Contacts/Locations, Study Status and Study Identification
7	○	○	November 4, 2008	Contacts/Locations, Study Status, Sponsor/Collaborators and Study Identification
8	○	○	December 1, 2008	Study Status and Contacts/Locations
9	○	○	January 5, 2009	Contacts/Locations and Study Status
10	○	○	February 5, 2009	Contacts/Locations and Study Status
11	○	○	March 5, 2009	Contacts/Locations, Study Status, Eligibility and Sponsor/Collaborators
12	○	○	April 2, 2009	Contacts/Locations, Study Status and Eligibility
13	○	○	May 4, 2009	Study Status
14	○	○	June 4, 2009	Contacts/Locations, Study Status and Eligibility
15	○	○	July 3, 2009	Contacts/Locations, Study Status and Eligibility
16	○	○	September 1, 2009	Contacts/Locations, Study Status and Eligibility

Version	A	B	Submitted Date	Changes
17	○	○	September 23, 2009	Recruitment Status, Contacts/Locations and Study Status
18	○	○	November 19, 2009	Study Status
19	○	○	February 19, 2010	Contacts/Locations, Study Status, Arms and Interventions, Study Design and Study Identification
20	○	○	July 9, 2010	Contacts/Locations and Study Status
21	○	○	October 6, 2010	Study Status
22	○	○	November 30, 2010	Contacts/Locations, Study Status and Study Design
23	○	○	February 21, 2011	Study Status
24	○	○	May 23, 2011	Study Status, Contacts/Locations, Sponsor/Collaborators and Study Identification
25	○	○	June 6, 2011	Contacts/Locations, Arms and Interventions, Study Status, Study Identification, Outcome Measures and Sponsor/Collaborators
26	○	○	December 16, 2011	Recruitment Status, Study Status, Outcome Measures, Arms and Interventions, Study Identification, Results, References, Contacts/Locations, Eligibility and Study Description
27	◉	◉	February 27, 2012	Study Status and More Information
28	○	○	March 12, 2013	Reported Adverse Events, Contacts/Locations, Study Status, More Information and References
29	○	○	April 25, 2014	Sponsor/Collaborators, Study Status, More Information, Baseline Characteristics and References
30	○	○	November 28, 2014	Study Status, More Information and References

Compare

Comparison Format: (•) Merged ( ) Side-by-Side

Scroll up to access the controls

Study NCT00637377

Submitted Date: February 27, 2012 (v27)

Study Identification

Unique Protocol ID: 91689

Brief Title: Vascular Endothelial Growth Factor (VEGF) Trap-Eye: Investigation of Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) (VIEW 2)

Official Title: A Randomized, Double Masked, Active Controlled, Phase 3 Study of the Efficacy, Safety, and Tolerability of Repeated Doses of Intravitreal VEGF Trap in Subjects With Neovascular Age-related Macular Degeneration (AMD)

Secondary IDs: 2007-000583-25 [EudraCT Number]

Study Status

Record Verification: February 2012

Overall Status: Completed

Study Start: April 2008

Primary Completion: September 2010 [Actual]

Study Completion: August 2011 [Actual]

First Submitted: March 12, 2008

First Submitted that Met QC Criteria:	March 17, 2008
First Posted:	March 18, 2008 [Estimate]
Results First Submitted:	December 16, 2011
Results First Submitted that Met QC Criteria:	December 16, 2011
Results First Posted:	January 23, 2012 [Estimate]
Last Update Submitted that Met QC Criteria:	February 27, 2012
Last Update Posted:	February 28, 2012 [Estimate]

Sponsor/Collaborators

Sponsor:	Bayer
Responsible Party:	
Collaborators:	Regeneron Pharmaceuticals

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary: This study is a phase III, double-masked, randomized, study of the efficacy and safety of VEGF Trap-Eye in patients with neovascular age-related macular degeneration. Approximately 1200 patients will be randomized in Europe, Asia, Japan, Australia and South America.

Detailed Description: Data of this trial ("VIEW 2") was pooled with data of a sister trial ("VIEW 1", NCT00509795), and an integrated analyses of the combined data was performed.

Conditions

Conditions: Macular Degeneration

Keywords: Eye diseases
Vision Impairment and Blindness
Eyes and Vision
Seniors
Neovascular Age-Related Macular Degeneration (AMD)
Retinal Disease

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 3

Interventional Study Model: Parallel Assignment

Number of Arms: 4

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 1240 [Actual]

Arms and Interventions

Arms	Assigned Interventions

Arms	Assigned Interventions
Active Comparator: Ranibizumab 0.5mg Q4 Participants received a 0.5 mg dose of Ranibizumab via intravitreal (IVT) injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Drug: Ranibizumab Participants received a 0.5 mg dose of Ranibizumab via intravitreal (IVT) injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4 Participants received a 2.0 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 2.0 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4 Participants received a 0.5 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 0.5 mg dose of Aflibercept Injection administered every 4 weeks for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Experimental: Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8 Participants received a 2.0 mg dose of Aflibercept Injection administered every 8 weeks (including one additional 2,0 mg dose at Week 4) for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.	Biological: Aflibercept Injection (EYLEA, VEGF Trap-Eye, BAY86-5321) Participants received a 2.0 mg dose of Aflibercept Injection administered every 8 weeks (including one additional 2,0 mg dose at Week 4) for the first year. Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 50 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Signed informed consent.
- Men and women >/=50 years of age.
- Active primary or recurrent subfoveal CNV lesions secondary to AMD, including juxtafoveal lesions that affect the fovea as evidenced by Fluorescein angiography (FA) in the study eye.
- ETDRS Best-Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye at 4 meters.
- Willing, committed, and able to return for ALL clinic visits and complete all study-related procedures.
- Able to read, (or, if unable to read due to visual impairment, be read to verbatim by the person administering the informed consent or a family member) understand and willing to sign the informed consent form.

Exclusion Criteria:

- Any prior ocular (in the study eye) or systemic treatment or surgery for neovascular AMD, except dietary supplements or vitamins.

- Any prior or concomitant therapy with another investigational agent to treat neovascular AMD in the study eye.
- Any prior treatment with anti-VEGF agents in the study eye.
- Total lesion size >12 disc areas (30.5 mm, including blood, scars and neovascularization) as assessed by FA in the study eye.
- Subretinal hemorrhages that is either 50% or more of the total lesion area, or if the blood is under the fovea and is 1 or more disc areas in size in the study eye (if the blood is under the fovea, then the fovea must be surrounded by 270 degrees by visible CNV).
- Scar or fibrosis making up >50% of the total lesion in the study eye.
- Scar, fibrosis, or atrophy involving the center of the fovea in the study eye.
- Presence of retinal pigment epithelial tears or rips involving the macula in the study eye.
- History of any vitreous hemorrhage within 4 weeks prior to Visit 1 in the study eye.
- Presence of other causes of CNV in the study eye.
- Prior vitrectomy in the study eye.
- History of retinal detachment or treatment or surgery for retinal detachment in the study eye.
- Any history of macular hole of stage 2 and above in the study eye.
- Any intraocular or periocular surgery within 3 months of Day 1 on the study eye, except lid surgery, which may not have taken place within 1 month of Day 1, as long as it is unlikely to interfere with the injection.
- History or clinical evidence of diabetic retinopathy, diabetic macular edema or any retinal vascular disease other than AMD in either eye.

Contacts/Locations

Study Officials: Bayer Study Director
Study Director
Bayer

Locations: **Argentina, Ciudad Auton. de Buenos Aires**

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1015ABO

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1023AAQ

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1122AAI

Buenos Aires, Ciudad Auton. de Buenos Aires, Argentina, C1181ACH

Argentina, Santa Fe

Rosario, Santa Fe, Argentina, S2000ANJ

Argentina

Córdoba, Argentina, X5000IIT

Australia, New South Wales

Chatswood, New South Wales, Australia, 2067

Sydney, New South Wales, Australia, 2000

Westmead, New South Wales, Australia, 2145

Australia, Victoria

East Melbourne, Victoria, Australia, 3002

Parkville, Victoria, Australia, 3050

Australia, Western Australia

Nedlands, Western Australia, Australia, 6009

Australia

Parramatta, Australia, 2150

Austria

Innsbruck, Austria, 6020

Linz, Austria, 4021

Wien, Austria, 1090

Belgium

Liege, Belgium, 4000

Brazil, Sao Paulo

Ribeirão Preto, Sao Paulo, Brazil, 14048-900

São Paulo, Sao Paulo, Brazil, 05651-901

Brazil

Minas Gerais, Brazil, 30150-270

Sao Paulo, Brazil, 04023-062

Colombia, Antioquia

Medellín, Antioquia, Colombia

Colombia, Cauca

Cali, Cauca, Colombia

Colombia, Distrito Capital de Bogotá

Bogota, Distrito Capital de Bogotá, Colombia

Czech Republic

Brno, Czech Republic, 63400

Olonouc, Czech Republic, 77520

Praha 10, Czech Republic, 10034

Praha 4, Czech Republic, 14000

Usti nad Labem, Czech Republic, 401 13

France, Cedex 12

Paris, Cedex 12, France, 75557

France, Cedex 1

Nantes, Cedex 1, France, 44093

France

Besancon, France, 25030

Bordeaux, France, 33000

Dijon, France, 21079

Lyon, France, 69003

Lyon, France, 69006

Marseille, France, 13008

Paris, France, 75010

Paris, France, 75015

Germany, Baden-Württemberg

Freiburg, Baden-Württemberg, Germany, 79106

Heidelberg, Baden-Württemberg, Germany, 69120

Tübingen, Baden-Württemberg, Germany, 72076

Germany, Bayern

München, Bayern, Germany, 81675

Regensburg, Bayern, Germany, 93053

Germany, Hessen

Darmstadt, Hessen, Germany, 64297

Germany, Nordrhein-Westfalen

Aachen, Nordrhein-Westfalen, Germany, 52074

Bonn, Nordrhein-Westfalen, Germany, 53105

Essen, Nordrhein-Westfalen, Germany, 45122

Köln, Nordrhein-Westfalen, Germany, 50924

Münster, Nordrhein-Westfalen, Germany, 48145

Germany, Rheinland-Pfalz

Ludwigshafen, Rheinland-Pfalz, Germany, 67063

Mainz, Rheinland-Pfalz, Germany, 55131

Germany, Saarland

Homburg, Saarland, Germany, 66421

Germany, Sachsen

Dresden, Sachsen, Germany, 01307

Dresden, Sachsen, Germany, 06067

Leipzig, Sachsen, Germany, 04103

Germany, Schleswig-Holstein

Kiel, Schleswig-Holstein, Germany, 24105

Lübeck, Schleswig-Holstein, Germany, 23538

Germany

Berlin, Germany, 12200

Hamburg, Germany, 20251

Hungary

Budapest, Hungary, 1083

Budapest, Hungary, 1106

Budapest, Hungary, 1133

Veszprem, Hungary, 8200

India, Gujrat

Ahemedabad - 4, Gujrat, India, 380009

India, Maharashtra

Wadala, Mumbai, Maharashtra, India, 400031

India, Tamil Nadu

Chennai, Tamil Nadu, India, 600 006

Coimbatore, Tamil Nadu, India, 641014

Madurai, Tamil Nadu, India, 625 020

Pondicherry, Tamil Nadu, India, 600007

India

Bangalore, India, 560010

Chandigarh, India, 160012

Hyderabad, India, 500 034

Kerala, India, 683572

Kolkata, India, 700073

Mumbai, India, 400 050

New Delhi, India, 110002

New Delhi, India, 110029

Orissa, India, 751 024

Israel

Afula, Israel

Beer Sheva, Israel

Haifa, Israel, 34362

Jerusalem, Israel, 91120

Kfar Saba, Israel

Petach Tikva, Israel, 49100

Rehovot, Israel, 76100

Tel Aviv, Israel, 64239

Tel Hashomer, Israel

Zrifin, Israel, 70300

Italy

Ancona, Italy, 60126

Bari, Italy, 70124

Catania, Italy, 95123

Genova, Italy, 16132

Milano, Italy, 20122

Milano, Italy, 20132

Milano, Italy, 20157

Padova, Italy, 35128

Roma, Italy, 00133

Roma, Italy, 00168

Roma, Italy, 00198

Torino, Italy, 10122

Udine, Italy, 33100

Varese, Italy, 21100

Verona, Italy, 37121

Japan, Aichi

Nagoya, Aichi, Japan, 466-8560

Nagoya, Aichi, Japan, 467-8602

Japan, Chiba

Urayasu, Chiba, Japan, 279-0021

Japan, Gunma

Maebashi, Gunma, Japan, 371-8511

Japan, Hokkaido

Sapporo, Hokkaido, Japan, 060-8604

Japan, Kagawa

Kita, Kagawa, Japan, 761-0793

Japan, Osaka

Hirakata, Osaka, Japan, 573-1191

Suita, Osaka, Japan, 565-0871

Japan, Shiga

Otsu, Shiga, Japan, 520-2192

Japan, Tokyo

Chiyoda-ku, Tokyo, Japan, 101-8309

Shinjuku-ku, Tokyo, Japan, 160-8582

Japan

Fukuoka, Japan, 812-8582

Fukushima, Japan, 960-1295

Kagoshima, Japan, 890-8520

Kyoto, Japan, 606-8507

Korea, Republic of, Gyeonggido

Seongnam, Gyeonggido, Korea, Republic of, 463 707

Korea, Republic of

Incheon, Korea, Republic of, 405-760

Seoul, Korea, Republic of, 110 744

Seoul, Korea, Republic of, 137 701

Seoul, Korea, Republic of, 138-736

Seoul, Korea, Republic of, 152-703

Latvia

Riga, Latvia, 1002

Riga, Latvia, 1009

Riga, Latvia, 1050

Mexico, Distrito Federal

Mexico City, Distrito Federal, Mexico, 06800

Mexico, Jalisco

Zapopan, Jalisco, Mexico, 45060

Mexico, México

Metepec, México, Mexico, 52140

Mexico, Nuevo Leon

Monterrey, Nuevo Leon, Mexico, 64060

Monterrey, Nuevo Leon, Mexico, 64480

Mexico

Chihuahua, Mexico, 31238

Mexico City, Mexico, 06030

México D.F., Mexico, 04030

Netherlands, ZA

Leiden, ZA, Netherlands, 2333

Netherlands

Amsterdam, Netherlands, 1100 DD

Groningen, Netherlands, 9713 GZ

Nijmegen, Netherlands, 6525 EX

Rotterdam, Netherlands, 3000 CA

Poland

Bydgoszcz, Poland, 85-631

Gdansk, Poland, 80-952

Katowice, Poland, 40-760

Poznan, Poland, 61-848

Warszaa, Poland, 02-005

Warszawa, Poland, 00-416

Wroclaw, Poland, 50-368

Portugal

Coimbra, Portugal, 3000-548

Porto, Portugal, 4200-319

Singapore

Singapore, Singapore, 119074

Singapore, Singapore, 159964

Singapore, Singapore, 168751

Singapore, Singapore, 308433

Slovakia

Banska Bystrica, Slovakia, 97517

Bratislava, Slovakia, 81369

Spain, A Coruña

Santiago de Compostela, A Coruña, Spain, 15705

Spain, Asturias

Oviedo, Asturias, Spain, 33012

Spain, Navarra

Pamplona, Navarra, Spain, 31008

Spain

Alicante, Spain, 03016

Barcelona, Spain, 08017

Barcelona, Spain, 08022

Barcelona, Spain, 08035

Barcelona, Spain, 08036

Madrid, Spain, 28002

Madrid, Spain, 28046

Malaga, Spain, 29010

Sevilla, Spain, 41009

Sevilla, Spain, 41013

Valencia, Spain, 46014

Valencia, Spain, 46015

Valladolid, Spain, 47005

Sweden

Linköping, Sweden, 58185

Stockholm, Sweden, 11282

Örebro, Sweden, 70185

Switzerland

Basel, Switzerland, 4031

Bern, Switzerland, 3010

Genève, Switzerland, 1211

Zürich, Switzerland, 8091

United Kingdom, Hampshire

Southampton, Hampshire, United Kingdom, SO16 6YD

United Kingdom, Surrey

Camberley, Surrey, United Kingdom, GU16 5UJ

United Kingdom

Aberdeen, United Kingdom, AB25 2ZN

Belfast, United Kingdom, BT12 6BA

Birmingham, United Kingdom, B4 7ET

Liverpool, United Kingdom, L7 8XP

London, United Kingdom, NW1 5QH

London, United Kingdom, SE5 9RS

Plymouth, United Kingdom, PL4 6PL

Torquay, United Kingdom, TQ2 7AA

IPDSharing

Plan to Share IPD:

References

Citations:

Links: URL: http://clinicaltrials.gov/ct2/show/NCT00509795?term=NCT00509795;rank=1

Description: Click here to view the data of the twin trial conducted by the collaboration partner.

Available IPD/Information:

Study Results

Participant Flow

Recruitment Details	The study was conducted at 186 study centers in 26 countries. Recruitment period: 21 Apr 2008 - 4 Sep 2009.
Pre-assignment Details	2031 participants were screened, 1240 were randomized and 1204 received at least 1 dose of study drug. 1204 participants were included in the Safety-Analysis Set (SAS). 1202 participants with at least 1 post-baseline measurement were included in the Full-Analysis Set (FAS).

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Overall Study

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Started	303	313	311	313
Participants Received Treatment	291 [1]	309 [1]	297 [1]	307 [1]
Participants Treated (FAS)	291	309	296	306
Completed	276	281	274	284
Not Completed	27	32	37	29
Adverse Event	2	6	8	9
Death	1	3	2	1
Lack of Efficacy	0	0	1	1
Lost to Follow-up	4	1	2	2
Protocol Violation	2	1	1	0
Withdrawal by Subject	11	15	13	11
Other (no further information available)	7	6	10	5

[1] safety population

Baseline Characteristics

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Baseline Measures

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Overall Number of Participants	291	309	296	306	1202

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Age Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		73.0 (9.0)	74.1 (8.5)	74.7 (8.6)	73.8 (8.6)	73.9 (8.7)
Sex: Female, Male [1] Measure type: Count of Participants Unit of measure: Participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
	Female	169 58.08%	176 56.96%	147 49.66%	175 57.19%	667 55.49%
	Male	122 41.92%	133 43.04%	149 50.34%	131 42.81%	535 44.51%
		[1] Measure Description: Information retrieved from all baseline participants.				
Ethnicity [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Not Hispanic or Latino		239 82.13%	259 83.82%	241 81.42%	251 82.03%	990 82.36%
Hispanic or Latino		52 17.87%	50 16.18%	55 18.58%	55 17.97%	212 17.64%
		[1] Measure Description: Information retrieved from all baseline participants.				
Race [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
White		213 73.2%	226 73.14%	219 73.99%	217 70.92%	875 72.8%
Black or African American		1 0.34%	0 0%	1 0.34%	2 0.65%	4 0.33%

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Asian		60 20.62%	67 21.68%	61 20.61%	69 22.55%	257 21.38%
Missing		17 5.84%	16 5.18%	15 5.07%	18 5.88%	66 5.49%
		[1] Measure Description: Information retrieved from all baseline participants.				
National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) total score [1]	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Mean (Standard Deviation) Unit of measure: scores on a scale		72.90 (19.09)	70.27 (19.41)	74.04 (18.22)	71.30 (19.06)	72.10 (18.99)
		[1] Measure Description: Information retrieved from 1201/1202 baseline participants. The possible range of the NEI VFQ-25 total score is between 0 (worst possible) and 100 (best possible).				
Area of Choroidal Neovascularization (CNV) [1]	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Mean (Standard Deviation) Unit of measure: mm^2		7.59 (5.34)	8.25 (5.77)	7.70 (5.26)	7.75 (5.52)	7.83 (5.48)
		[1] Measure Description: Information retrieved from 1200/1202 baseline participants.				

		Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
Baseline lesion type [1] Measure type: Number Unit of measure: participants	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
Predominantly classic		70 24.05%	72 23.3%	80 27.03%	88 28.76%	310 25.79%
Minimally classic		104 35.74%	112 36.25%	103 34.8%	106 34.64%	425 35.36%
Occult		116 39.86%	123 39.81%	113 38.18%	110 35.95%	462 38.44%
Missing		1 0.34%	2 0.65%	0 0%	2 0.65%	5 0.42%
		[1] Measure Description: Information retrieved from 1197/1202 baseline participants.				
Baseline total lesion size [1] Mean (Standard Deviation) Unit of measure: mm^2	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		8.01 (5.74)	8.72 (6.14)	8.17 (5.51)	8.22 (5.87)	8.28 (5.82)
		[1] Measure Description: Information retrieved from 1198/1202 baseline participants.				
Best Corrected Visual Acuity (BCVA), assessed by ETDRS chart [1] Mean (Standard Deviation)	Number Analyzed	291 Participants	309 Participants	296 Participants	306 Participants	1202 Participants
		53.8 (13.5)	52.8 (13.9)	51.6 (14.2)	51.6 (13.9)	52.4 (13.9)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Total
[1]	Measure Description: Information retrieved from all baseline participants. Only participants with a ETDRS (Early Treatment Diabetic Retinopathy Study) Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye at 4 meters were included; a higher score represents better functioning.				

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)
Measure Description	Maintenance of vision was defined as a loss of < 15 letters in the ETDRS (Early Treatment Diabetic Retinopathy Study) letter score (defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning. Nominator = (Number of participants who maintained vision * 100); Denominator = Number of participants analyzed.
Time Frame	At week 52

Analysis Population Description

Per-Protocol Set (PPS); imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	269	274	268	270
Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF) Measure Type: Number Unit of Measure: Percentage of participants	94.42	95.62	96.27	95.56

Statistical Analysis 1 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 2mg Q4, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 2mg Q4).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.20
	Confidence Interval	(2-sided) 95% -4.86 to 2.46
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 2mg Q4 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

Statistical Analysis 2 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 0.5mg Q4, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 0.5mg Q4).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.84
	Confidence Interval	(2-sided) 95% -5.40 to 1.71
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 0.5mg Q4 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

Statistical Analysis 3 for Percentage of Participants Who Maintained Vision at Week 52 - Last Observation Carried Forward (LOCF)

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	null hypothesis: pi ≤ pc-delta where pi is the probability that a participant maintained vision at week 52 under Aflibercept 2mg Q8, pc is the probability that a participant maintained vision at week 52 under Ranibizumab 0.5mg Q4 and delta is the non-inferiority margin. The null hypothesis is tested calculating a two-sided 95 % confidence using normal approximation of the difference of percentages of participants maintaining vision at week 52 (Ranibizumab 0.5mg Q4 minus Aflibercept 2mg Q8).
	Type of Statistical Test	Non-Inferiority or Equivalence
	Comments	The non-inferiority margin is set to 10. The power is 90 % according to the sample size estimation of the study protocol.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-1.13
	Confidence Interval	(2-sided) 95% -4.81 to 2.55
	Estimation Comments	The difference is calculated as Ranibizumab minus Aflibercept. A negative value favors the Aflibercept 2mg Q8 group. As adjustment of multiple comparisons a conditional sequence of statistical hypotheses is used with alpha = 0.05.

2. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning.

Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set (FAS); imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	291	309	296	306
Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: Letters correctly read	9.4 (13.5)	7.6 (12.6)	9.7 (14.1)	8.9 (14.4)

Statistical Analysis 1 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.076
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.9484
	Confidence Interval	(2-sided) 95% -4.1009 to 0.2040
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.9555
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.0620
	Confidence Interval	(2-sided) 95% -2.2398 to 2.1158
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 0.5mg Q4

Statistical Analysis 3 for Mean Change From Baseline in Best Corrected Visual Acuity (BCVA) as Measured by ETDRS Letter Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline ETDRS letter score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.4131
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.9014
	Confidence Interval	(2-sided) 95% -3.0615 to 1.2587
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q8 group

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF
Measure Description	Defined study baseline range of ETDRS Best Corrected Visual Acuity letter score of 73 to 25 (= Acuity of 20/40 to 20/320) in the study eye; a higher score represents better functioning. Nominator = (Number of participants who maintained vision * 100); Denominator = Number of participants analyzed.
Time Frame	At week 52

Analysis Population Description

Full-Analysis Set; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	291	309	296	306
Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF Measure Type: Number Unit of Measure: Percentage of participants	34.02	29.45	34.80	31.37

Statistical Analysis 1 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.229
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-4.57
	Confidence Interval	(2-sided) 95% -12.02 to 2.88
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q4 group

Statistical Analysis 2 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.843
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	0.78
	Confidence Interval	(2-sided) 95% -6.91 to 8.46
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 0.5mg Q4 group

Statistical Analysis 3 for Percentage of Participants Who Gained at Least 15 Letters of Vision in the ETDRS Letter Score in the Study Eye at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The null hypothesis is that the two proportions are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.490
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	Chi-squared
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	-2.65
	Confidence Interval	(2-sided) 95% -10.18 to 4.88
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors the Aflibercept 2mg Q8 group

4. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF
Measure Description	The possible range of the NEI VFQ-25 total score is between 0 (worst possible) and 100 (best possible).
Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set with assessment for this outcome measure; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	287	304	290	299
Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: Scores on a scale	6.3 (14.8)	4.5 (15.0)	5.1 (13.7)	4.9 (14.7)

Statistical Analysis 1 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0097
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-2.7885
	Confidence Interval	(2-sided) 95% -4.9012 to -0.6757
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.3917
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.9320
	Confidence Interval	(2-sided) 95% -3.0658 to 1.2019
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 0.5mg Q4.

Statistical Analysis 3 for Mean Change From Baseline in National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) Total Score at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline NEI VFQ-25 total score as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0717
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.9470
	Confidence Interval	(2-sided) 95% -4.0659 to 0.1718
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A positive value favors Aflibercept 2mg Q8.

5. Secondary Outcome Measure:

Measure Title	Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF
Measure Description	CNV area values measured in square millimeters; lower values represent better outcomes.

Time Frame	Baseline and at week 52

Analysis Population Description

Full-Analysis Set with assessment for this outcome measure; imputation technique: LOCF

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Measured Values

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Overall Number of Participants Analyzed	278	294	287	289
Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF Measure Type: Mean (Standard Deviation) Unit of Measure: mm^2	-4.16 (5.90)	-5.95 (6.12)	-4.24 (6.13)	-5.16 (5.87)

Statistical Analysis 1 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0038
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-1.180
	Confidence Interval	(2-sided) 95% -1.979 to -0.382
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 2mg Q4.

Statistical Analysis 2 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.6784
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	0.170
	Confidence Interval	(2-sided) 95% -0.632 to 0.972
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 0.5mg Q4.

Statistical Analysis 3 for Mean Change From Baseline in Choroidal Neovascularization (CNV) Area at Week 52 - LOCF

Statistical Analysis Overview	Comparison Groups	Ranibizumab 0.5mg Q4, Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Comments	The pairwise comparison is performed as contrast statement in the analysis of covariance model with treatment group as fixed factor (all 4 treatment groups) and the baseline CNV area as covariate. The null hypothesis is that both mean changes are equal.
	Type of Statistical Test	Superiority or Other (legacy)
	Comments	[Not specified]

Statistical Test of Hypothesis	P-Value	0.0727
	Comments	as adjustment of multiple comparisons a conditional sequence of statistical hypotheses (a-priori ordered hypotheses) is used with alpha = 0.05.
	Method	ANCOVA
	Comments	[Not specified]

Method of Estimation	Estimation Parameter	Differences in Least Squares means
	Estimated Value	-0.733
	Confidence Interval	(2-sided) 95% -1.534 to 0.068
	Estimation Comments	The difference is calculated as Aflibercept minus Ranibizumab. A negative value favors Aflibercept 2mg Q8.

Reported Adverse Events

Time Frame	[Not specified]
Adverse Event Reporting Description	[Not specified]

Reporting Groups

	Description
Ranibizumab 0.5mg Q4	Participants received a dose of 0.5 mg Ranibizumab every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Participants received a dose of 2.0 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.
Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Participants received a dose of 0.5 mg Aflibercept Injection every 4 weeks for the first year (intravitreal [IVT] injection). Thereafter a dose may be administered as frequently as every 4 weeks, but no less frequently than every 12 weeks.

Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8	Participants received a dose of 2.0 mg Aflibercept Injection every 8 weeks (including one additional 2.0 mg dose at Week 4) for the first year (IVT injection) and were to receive sham injections at interim monthly visits. During the second year, participants received 2.0 mg aflibercept as frequently as every 4 weeks, but no less frequently than every 12 weeks.

All-Cause Mortality

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	/	/	/	/

Serious Adverse Events

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	36/291 (12.37%)	50/309 (16.18%)	42/297 (14.14%)	50/307 (16.29%)
Blood and lymphatic system disorders				
Anaemia [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Febrile neutropenia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cardiac disorders				
Acute coronary syndrome [A*]	0/291 (0%)	2/309 (0.65%)	2/297 (0.67%)	1/307 (0.33%)
Acute myocardial infarction [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Angina pectoris [A*]	1/291 (0.34%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Arteriosclerosis coronary artery [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Atrial fibrillation [A*]	2/291 (0.69%)	1/309 (0.32%)	0/297 (0%)	3/307 (0.98%)
Atrial flutter [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Atrioventricular block [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cardiac arrest [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cardiac failure [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Cardiopulmonary failure [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cardiovascular insufficiency [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Coronary artery disease [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Myocardial infarction [A*]	2/291 (0.69%)	1/309 (0.32%)	3/297 (1.01%)	3/307 (0.98%)
Myocardial ischaemia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Palpitations [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Pericarditis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Supraventricular tachycardia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Ear and labyrinth disorders				
Tympanic membrane disorder [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Vertigo [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Eye disorders				
Cataract (Fellow Eye) [A*]	3/291 (1.03%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Cataract (Study Eye) [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Cataract cortical (Study Eye) [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Cataract nuclear (Study Eye) [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Choroidal detachment (Study Eye) [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Choroidal neovascularisation (Fellow Eye) [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Hyphaema (Study Eye) [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Macular cyst (Study Eye) [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Macular degeneration (Fellow Eye) [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	1/307 (0.33%)
Macular degeneration (Study Eye) [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Macular hole (Study Eye) [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Maculopathy (Fellow Eye) [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Posterior capsule opacification (Study Eye) [A*]	2/291 (0.69%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Retinal degeneration (Study Eye) [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Retinal detachment (Study Eye) [A*]	1/291 (0.34%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Retinal haemorrhage (Fellow Eye) [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Retinal haemorrhage (Study Eye) [A*]	1/291 (0.34%)	2/309 (0.65%)	1/297 (0.34%)	1/307 (0.33%)
Retinal pigment epithelial tear (Study Eye) [A*]	1/291 (0.34%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Retinal pigment epitheliopathy (Fellow Eye) [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Retinal pigment epitheliopathy (Study Eye) [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Retinal vein occlusion (Fellow Eye) [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Visual acuity reduced (Fellow Eye) [A*]	0/291 (0%)	3/309 (0.97%)	0/297 (0%)	1/307 (0.33%)
Visual acuity reduced (Study Eye) [A*]	2/291 (0.69%)	1/309 (0.32%)	1/297 (0.34%)	5/307 (1.63%)
Vitreous haemorrhage (Fellow Eye) [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Gastrointestinal disorders				
Anal fistula [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Colitis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Constipation [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Diverticulum intestinal [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gastric ulcer [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Gastritis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Gastritis erosive [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Inguinal hernia [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	1/307 (0.33%)
Intestinal obstruction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Large intestine perforation [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lower gastrointestinal haemorrhage [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Pancreatitis acute [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Small intestinal obstruction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
General disorders				
Chest pain [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Death [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Device dislocation [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Device malfunction [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Oedema peripheral [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Pyrexia [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	0/307 (0%)
Hepatobiliary disorders				
Cholecystitis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cholecystitis acute [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cholelithiasis [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Infections and infestations				
Appendicitis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Bronchitis [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Dysentery [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Escherichia sepsis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gastroenteritis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Gastroenteritis norovirus [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Gastroenteritis salmonella [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Pneumonia [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	2/307 (0.65%)
Pneumonia pneumococcal [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Postoperative wound infection [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Respiratory tract infection [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Septic shock [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Urinary tract infection [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Injury, poisoning and procedural complications				
Accident [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Ankle fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Burns second degree [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Clavicle fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Concussion [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Contusion [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Fall [A*]	2/291 (0.69%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Femoral neck fracture [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Femur fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Graft thrombosis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Head injury [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Injury [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Joint injury [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Lower limb fracture [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Lumbar vertebral fracture [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Macular scar [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Meniscus lesion [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	2/307 (0.65%)
Post procedural complication [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Radius fracture [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Road traffic accident [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Skull fractured base [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Subdural haematoma [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Upper limb fracture [A*]	0/291 (0%)	0/309 (0%)	2/297 (0.67%)	0/307 (0%)
Wound haemorrhage [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Investigations				
Blood osmolarity decreased [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Electrocardiogram QT prolonged [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Intraocular pressure increased [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Metabolism and nutrition disorders				
Dehydration [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Diabetes mellitus [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hyperglycaemia [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Arthritis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Dupuytren's contracture [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Intervertebral disc protrusion [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Neck pain [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Rheumatoid arthritis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Sjogren's syndrome [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Synovitis [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Acute myeloid leukaemia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Basal cell carcinoma [A*]	1/291 (0.34%)	0/309 (0%)	2/297 (0.67%)	0/307 (0%)
Bladder cancer [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Bladder cancer recurrent [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Breast cancer [A*]	1/291 (0.34%)	0/309 (0%)	3/297 (1.01%)	1/307 (0.33%)
Colon cancer [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Colon cancer metastatic [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Lung cancer metastatic [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lung carcinoma cell type unspecified stage IV [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Lung neoplasm malignant [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Oesophageal carcinoma [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Ovarian cancer [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Prostate cancer metastatic [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Squamous cell carcinoma [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Nervous system disorders				
Brain oedema [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cerebral infarction [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Cerebrovascular accident [A*]	1/291 (0.34%)	1/309 (0.32%)	0/297 (0%)	2/307 (0.65%)
Epilepsy [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Headache [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Hypertensive encephalopathy [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Lacunar infarction [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Nerve root compression [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Petit mal epilepsy [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Syncope [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Transient ischaemic attack [A*]	0/291 (0%)	2/309 (0.65%)	0/297 (0%)	0/307 (0%)
VIIth nerve paralysis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Psychiatric disorders				
Depression [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Renal and urinary disorders				
Renal failure [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Urinary tract obstruction [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Reproductive system and breast disorders				
Benign prostatic hyperplasia [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Uterine haemorrhage [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Respiratory, thoracic and mediastinal disorders				
Acute pulmonary oedema [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Chronic obstructive pulmonary disease [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)
Cough [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Dyspnoea [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Pleurisy [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Pneumothorax [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Sleep apnoea syndrome [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Skin and subcutaneous tissue disorders				

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Dermal cyst [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Dermatitis allergic [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Erythema multiforme [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Rash [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Skin necrosis [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Skin ulcer [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Surgical and medical procedures				
Blepharoplasty [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Cataract operation [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	0/307 (0%)
Haematoma evacuation [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hip surgery [A*]	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Strangulated hernia repair [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	0/307 (0%)
Vaginal operation [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Vascular disorders				
Circulatory collapse [A*]	0/291 (0%)	1/309 (0.32%)	1/297 (0.34%)	0/307 (0%)
Haematoma [A*]	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)
Hypertension [A*]	0/291 (0%)	0/309 (0%)	1/297 (0.34%)	1/307 (0.33%)
Hypertensive crisis [A*]	0/291 (0%)	1/309 (0.32%)	0/297 (0%)	1/307 (0.33%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Peripheral artery aneurysm A*	0/291 (0%)	0/309 (0%)	0/297 (0%)	1/307 (0.33%)
Varicose vein A*	1/291 (0.34%)	0/309 (0%)	0/297 (0%)	0/307 (0%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA (13.1)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	208/291 (71.48%)	209/309 (67.64%)	209/297 (70.37%)	217/307 (70.68%)
Cardiac disorders				
Atrioventricular block first degree A*	12/291 (4.12%)	22/309 (7.12%)	18/297 (6.06%)	17/307 (5.54%)
Eye disorders				
Cataract (Study Eye) A*	14/291 (4.81%)	17/309 (5.5%)	12/297 (4.04%)	13/307 (4.23%)
Choroidal neovascularisation (Fellow Eye) A*	14/291 (4.81%)	14/309 (4.53%)	15/297 (5.05%)	17/307 (5.54%)
Conjunctival haemorrhage (Study Eye) A*	23/291 (7.9%)	24/309 (7.77%)	37/297 (12.46%)	30/307 (9.77%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Detachment of retinal pigment epithelium (Study Eye) [A*]	26/291 (8.93%)	26/309 (8.41%)	24/297 (8.08%)	25/307 (8.14%)
Eye pain (Study Eye) [A*]	27/291 (9.28%)	33/309 (10.68%)	22/297 (7.41%)	21/307 (6.84%)
Macular cyst (Study Eye) [A*]	15/291 (5.15%)	6/309 (1.94%)	7/297 (2.36%)	6/307 (1.95%)
Macular degeneration (Fellow Eye) [A*]	18/291 (6.19%)	17/309 (5.5%)	25/297 (8.42%)	33/307 (10.75%)
Macular degeneration (Study Eye) [A*]	27/291 (9.28%)	28/309 (9.06%)	27/297 (9.09%)	33/307 (10.75%)
Ocular hyperaemia (Study Eye) [A*]	18/291 (6.19%)	13/309 (4.21%)	13/297 (4.38%)	9/307 (2.93%)
Retinal cyst (Study Eye) [A*]	10/291 (3.44%)	16/309 (5.18%)	14/297 (4.71%)	11/307 (3.58%)
Retinal degeneration (Study Eye) [A*]	23/291 (7.9%)	27/309 (8.74%)	20/297 (6.73%)	18/307 (5.86%)
Retinal haemorrhage (Fellow Eye) [A*]	21/291 (7.22%)	17/309 (5.5%)	12/297 (4.04%)	21/307 (6.84%)
Retinal haemorrhage (Study Eye) [A*]	39/291 (13.4%)	41/309 (13.27%)	39/297 (13.13%)	37/307 (12.05%)
Retinal oedema (Study Eye) [A*]	18/291 (6.19%)	17/309 (5.5%)	14/297 (4.71%)	23/307 (7.49%)
Retinal pigment epitheliopathy (Study Eye) [A*]	25/291 (8.59%)	22/309 (7.12%)	19/297 (6.4%)	24/307 (7.82%)
Visual acuity reduced (Fellow Eye) [A*]	10/291 (3.44%)	10/309 (3.24%)	13/297 (4.38%)	19/307 (6.19%)

	Ranibizumab 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 0.5mg Q4	Aflibercept Injection (EYLEA, VEGF Trap-Eye) 2mg Q8
Visual acuity reduced (Study Eye) A*	19/291 (6.53%)	25/309 (8.09%)	33/297 (11.11%)	30/307 (9.77%)
Vitreous detachment (Study Eye) A*	10/291 (3.44%)	19/309 (6.15%)	10/297 (3.37%)	15/307 (4.89%)
General disorders				
Pyrexia A*	9/291 (3.09%)	7/309 (2.27%)	15/297 (5.05%)	5/307 (1.63%)
Infections and infestations				
Influenza A*	8/291 (2.75%)	14/309 (4.53%)	8/297 (2.69%)	17/307 (5.54%)
Nasopharyngitis A*	28/291 (9.62%)	15/309 (4.85%)	26/297 (8.75%)	19/307 (6.19%)
Investigations				
Intraocular pressure increased A*	23/291 (7.9%)	30/309 (9.71%)	21/297 (7.07%)	22/307 (7.17%)
Nervous system disorders				
Headache A*	12/291 (4.12%)	9/309 (2.91%)	12/297 (4.04%)	17/307 (5.54%)
Vascular disorders				
Hypertension A*	25/291 (8.59%)	22/309 (7.12%)	19/297 (6.4%)	19/307 (6.19%)

* Indicates events were collected by non-systematic methods.

A Term from vocabulary, MedDRA (13.1)

Limitations and Caveats

The conditional sequence of hypothesis testing had to stop after testing the first superiority hypothesis. Therefore, all further statistical tests are exploratory tests.

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Official Title: Therapeutic Area Head
Organization: BAYER
Phone:
Email: clinical-trials-contact@bayerhealthcare.com

Scroll up to access the controls Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00789477

DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)

Latest version (submitted August 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	November 7, 2008	None (earliest Version on record)
2	○	○	December 5, 2008	Recruitment Status, Arms and Interventions, Contacts/Locations, Study Status, Outcome Measures, Oversight, Eligibility and Study Identification
3	○	○	February 5, 2009	Contacts/Locations, Study Status and Study Identification

Version	A	B	Submitted Date	Changes
4	○	○	February 11, 2009	Contacts/Locations, Study Status and Study Identification
5	○	○	February 13, 2009	Study Identification, Contacts/Locations and Study Status
6	○	○	March 12, 2009	Study Status and Contacts/Locations
7	○	○	April 24, 2009	Contacts/Locations and Study Status
8	○	○	May 27, 2009	Study Status and Contacts/Locations
9	○	○	June 2, 2009	Contacts/Locations and Study Status
10	○	○	June 18, 2009	Contacts/Locations and Study Status
11	○	○	July 14, 2009	Recruitment Status, Study Status and Contacts/Locations
12	○	○	November 18, 2010	Study Status
13	○	○	January 24, 2011	Recruitment Status, Study Status and Study Design
14	◉	◉	May 2, 2011	Study Status, Arms and Interventions
15	○	○	September 27, 2013	Sponsor/Collaborators and Study Status
16	○	○	August 13, 2014	Study Status
17	○	○	August 28, 2014	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Contacts/Locations, Study Design, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Study NCT00789477

Submitted Date: May 2, 2011 (v14)

Study Identification

Unique Protocol ID: VGFT-OD-0706

Brief Title: DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)

Official Title: A Double-Masked, Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap-Eye in Patients With Diabetic Macular Edema (DME)

Secondary IDs:

Study Status

Record Verification: May 2011

Overall Status: Completed

Study Start: December 2008

Primary Completion: December 2009 [Actual]

Study Completion: September 2010 [Actual]

First Submitted: November 7, 2008

First Submitted that Met QC Criteria: November 7, 2008

First Posted: November 11, 2008 [Estimate]

Certification/Extension First Submitted: April 19, 2011

Certification/Extension First Submitted that Met QC Criteria: May 2, 2011

Certification/Extension First Posted:	May 5, 2011 [Estimate]
Last Update Submitted that Met QC Criteria:	May 2, 2011
Last Update Posted:	May 5, 2011 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals
Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary:	This is a Phase 2, doubled-masked, randomized study of the efficacy and safety of VEGF Trap-Eye in subjects with diabetic macular edema. Approximately 200 subjects will be randomized in the US, Canada, Australia and EU.
Detailed Description:	Qualified subjects will be randomized to one of 5 treatment arms. The active (treatment) phase of the study will be 52 weeks, with a 6 month safety follow-up

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2

Interventional Study Model: Parallel Assignment

Number of Arms: 5

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Allocation: Randomized

Enrollment: 219 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 Dose 1	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 2 Dose 2	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 3 Dose 3	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 4 Dose 4	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Active Comparator: 5 Non-drug comparator	Procedure: macular laser therapy laser every 16 weeks as needed Other Names: • laser photocoagulation

Outcome Measures

Primary Outcome Measures:

1. Change in best corrected visual acuity
   Week 24

Secondary Outcome Measures:

2. Change from baseline in foveal thickness

Weeks 24 and 52

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Patients with clinically significant DME with central involvement
- Adults 18 years or older with type 1 or 2 diabetes mellitus with diabetic macular edema
- ETDRS BCVA: 20/40 to 20/320 (letter score of 73 to 24) in the study eye

Exclusion Criteria:

- History of vitreoretinal surgery in the study eye
- Panretinal laser photocoagulation or macular laser photocoagulation in the study eye within 3 months of screening
- Previous use of intraocular or periocular corticosteroids in the study eye within 3 months of screening
- Previous treatment with anti-angiogenic drugs in either eye (pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc) within 3 months of screening
- Uncontrolled diabetes mellitus
- Uncontrolled hypertension defined as systolic > 180mmHg or > 160 mmHg on 2 consecutive measurements or diastolic > 100 mmHg on optimal medical regimen
- Ocular disorders in the study eye, other than DME, that may confound interpretation of study results

Contacts/Locations

Study Officials: Robert L Vitti, MD
Study Director

Regeneron Pharmaceuticals

Locations: **United States, California**

Artesia, California, United States, 90701

Beverly Hills, California, United States, 90211

Mountain View, California, United States, 94040

Pasadena, California, United States, 91105

Sacramento, California, United States, 95819

Santa Ana, California, United States, 92705

United States, Connecticut

Hamden, Connecticut, United States, 06518

New London, Connecticut, United States, 06320

United States, Florida

Boynton Beach, Florida, United States, 33426

Fort Lauderdale, Florida, United States, 33334

Fort Myers, Florida, United States, 33912

Ocala, Florida, United States, 34474

Palm Beach Gardens, Florida, United States, 33410

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Hawaii

Honolulu, Hawaii, United States, 96815

United States, Indiana

Indianapolis, Indiana, United States, 46280

United States, Maine

Bangor, Maine, United States, 04401

United States, Maryland

Baltimore, Maryland, United States, 21287

United States, Massachusetts

Boston, Massachusetts, United States, 02114

United States, Michigan

Jackson, Michigan, United States, 48104

United States, Missouri

Kansas City, Missouri, United States, 64108

United States, Nebraska

Lincoln, Nebraska, United States, 68506

United States, New Jersey

New Brunswick, New Jersey, United States, 08901

Northfield, New Jersey, United States, 08225

Toms River, New Jersey, United States, 08753

United States, New York

Rochester, New York, United States, 14620

United States, North Carolina

Charlotte, North Carolina, United States, 28210

Raleigh, North Carolina, United States, 27607

United States, Ohio

Cincinnati, Ohio, United States, 45243

United States, Pennsylvania

Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

Greenville, South Carolina, United States, 29605

West Columbia, South Carolina, United States, 29169

United States, Tennessee

Nashville, Tennessee, United States, 37203

United States, Texas

Abilene, Texas, United States, 79606

Arlington, Texas, United States, 76012

Austin, Texas, United States, 78705

Houston, Texas, United States, 77030

McAllen, Texas, United States, 78503

San Antonio, Texas, United States, 78215

San Antonio, Texas, United States, 78240

United States, Utah

Salt Lake City, Utah, United States, 84107

Austria

Wien, Austria, 1090

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z 3N9

Victoria, British Columbia, Canada, V8V 4X3

Canada, Ontario

London, Ontario, Canada, N6A 4G5

Mississauga, Ontario, Canada, L4W 1W9

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00789477

DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)

Latest version (submitted August 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	November 7, 2008	None (earliest Version on record)
2	○	○	December 5, 2008	Recruitment Status, Arms and Interventions, Contacts/Locations, Study Status, Outcome Measures, Oversight, Eligibility and Study Identification
3	○	○	February 5, 2009	Contacts/Locations, Study Status and Study Identification

Version	A	B	Submitted Date	Changes
4	○	○	February 11, 2009	Contacts/Locations, Study Status and Study Identification
5	○	○	February 13, 2009	Study Identification, Contacts/Locations and Study Status
6	○	○	March 12, 2009	Study Status and Contacts/Locations
7	○	○	April 24, 2009	Contacts/Locations and Study Status
8	○	○	May 27, 2009	Study Status and Contacts/Locations
9	○	○	June 2, 2009	Contacts/Locations and Study Status
10	○	○	June 18, 2009	Contacts/Locations and Study Status
11	○	○	July 14, 2009	Recruitment Status, Study Status and Contacts/Locations
12	○	○	November 18, 2010	Study Status
13	◉	◉	January 24, 2011	Recruitment Status, Study Status and Study Design
14	○	○	May 2, 2011	Study Status, Arms and Interventions
15	○	○	September 27, 2013	Sponsor/Collaborators and Study Status
16	○	○	August 13, 2014	Study Status
17	○	○	August 28, 2014	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Contacts/Locations, Study Design, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00789477

Submitted Date: January 24, 2011 (v13)

Study Identification

Unique Protocol ID:	VGFT-OD-0706
Brief Title:	DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)
Official Title:	A Double-Masked, Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap-Eye in Patients With Diabetic Macular Edema (DME)
Secondary IDs:	

Study Status

Record Verification:	January 2011
Overall Status:	Completed
Study Start:	December 2008
Primary Completion:	September 2010 [Actual]
Study Completion:	September 2010 [Actual]
First Submitted:	November 7, 2008
First Submitted that Met QC Criteria:	November 7, 2008
First Posted:	November 11, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	January 24, 2011
Last Update Posted:	January 26, 2011 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals

Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary:	This is a Phase 2, doubled-masked, randomized study of the efficacy and safety of VEGF Trap-Eye in subjects with diabetic macular edema. Approximately 200 subjects will be randomized in the US, Canada, Australia and EU.
Detailed Description:	Qualified subjects will be randomized to one of 5 treatment arms. The active (treatment) phase of the study will be 52 weeks, with a 6 month safety follow-up

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Interventional Study Model:	Parallel Assignment
Number of Arms:	5
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation:	Randomized
Enrollment:	219 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 Dose 1	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 2 Dose 2	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 3 Dose 3	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 4 Dose 4	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Active Comparator: 5 Non-drug comparator	Procedure: Non-drug intervention laser every 16 weeks as needed Other Names: • laser photocoagulation

Outcome Measures

Primary Outcome Measures:

1. Change in best corrected visual acuity
   Week 24

Secondary Outcome Measures:

2. Change from baseline in foveal thickness
   Weeks 24 and 52

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Patients with clinically significant DME with central involvement
- Adults 18 years or older with type 1 or 2 diabetes mellitus with diabetic macular edema
- ETDRS BCVA: 20/40 to 20/320 (letter score of 73 to 24) in the study eye

Exclusion Criteria:

- History of vitreoretinal surgery in the study eye
- Panretinal laser photocoagulation or macular laser photocoagulation in the study eye within 3 months of screening
- Previous use of intraocular or periocular corticosteroids in the study eye within 3 months of screening
- Previous treatment with anti-angiogenic drugs in either eye (pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc) within 3 months of screening
- Uncontrolled diabetes mellitus
- Uncontrolled hypertension defined as systolic > 180mmHg or > 160 mmHg on 2 consecutive measurements or diastolic > 100 mmHg on optimal medical regimen
- Ocular disorders in the study eye, other than DME, that may confound interpretation of study results

Contacts/Locations

Study Officials: Robert L Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, California**

Artesia, California, United States, 90701

Beverly Hills, California, United States, 90211

Mountain View, California, United States, 94040

Pasadena, California, United States, 91105

Sacramento, California, United States, 95819

Santa Ana, California, United States, 92705

United States, Connecticut

Hamden, Connecticut, United States, 06518

New London, Connecticut, United States, 06320

United States, Florida

Boynton Beach, Florida, United States, 33426

Fort Lauderdale, Florida, United States, 33334

Fort Myers, Florida, United States, 33912

Ocala, Florida, United States, 34474

Palm Beach Gardens, Florida, United States, 33410

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Hawaii

Honolulu, Hawaii, United States, 96815

United States, Indiana

Indianapolis, Indiana, United States, 46280

United States, Maine

Bangor, Maine, United States, 04401

United States, Maryland

Baltimore, Maryland, United States, 21287

United States, Massachusetts

Boston, Massachusetts, United States, 02114

United States, Michigan

Jackson, Michigan, United States, 48104

United States, Missouri

Kansas City, Missouri, United States, 64108

United States, Nebraska

Lincoln, Nebraska, United States, 68506

United States, New Jersey

New Brunswick, New Jersey, United States, 08901

Northfield, New Jersey, United States, 08225

Toms River, New Jersey, United States, 08753

United States, New York

Rochester, New York, United States, 14620

United States, North Carolina

Charlotte, North Carolina, United States, 28210

Raleigh, North Carolina, United States, 27607

United States, Ohio

Cincinnati, Ohio, United States, 45243

United States, Pennsylvania

Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

Greenville, South Carolina, United States, 29605

West Columbia, South Carolina, United States, 29169

United States, Tennessee

Nashville, Tennessee, United States, 37203

United States, Texas

Abilene, Texas, United States, 79606

Arlington, Texas, United States, 76012

Austin, Texas, United States, 78705

Houston, Texas, United States, 77030

McAllen, Texas, United States, 78503

San Antonio, Texas, United States, 78215

San Antonio, Texas, United States, 78240

United States, Utah

Salt Lake City, Utah, United States, 84107

Austria

Wien, Austria, 1090

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z 3N9

Victoria, British Columbia, Canada, V8V 4X3

Canada, Ontario

London, Ontario, Canada, N6A 4G5

Mississauga, Ontario, Canada, L4W 1W9

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

Regeneron Ex. 2001
Fresenius v. Regeneron
IPR2025-01269
Page 2959 of 3000

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00789477

DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)

Latest version (submitted August 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	November 7, 2008	None (earliest Version on record)
2	○	○	December 5, 2008	Recruitment Status, Arms and Interventions, Contacts/Locations, Study Status, Outcome Measures, Oversight, Eligibility and Study Identification
3	○	○	February 5, 2009	Contacts/Locations, Study Status and Study Identification

Version	A	B	Submitted Date	Changes
4	○	○	February 11, 2009	Contacts/Locations, Study Status and Study Identification
5	○	○	February 13, 2009	Study Identification, Contacts/Locations and Study Status
6	○	○	March 12, 2009	Study Status and Contacts/Locations
7	○	○	April 24, 2009	Contacts/Locations and Study Status
8	○	○	May 27, 2009	Study Status and Contacts/Locations
9	○	○	June 2, 2009	Contacts/Locations and Study Status
10	○	○	June 18, 2009	Contacts/Locations and Study Status
11	○	○	July 14, 2009	Recruitment Status, Study Status and Contacts/Locations
12	◉	◉	November 18, 2010	Study Status
13	○	○	January 24, 2011	Recruitment Status, Study Status and Study Design
14	○	○	May 2, 2011	Study Status, Arms and Interventions
15	○	○	September 27, 2013	Sponsor/Collaborators and Study Status
16	○	○	August 13, 2014	Study Status
17	○	○	August 28, 2014	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Contacts/Locations, Study Design, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00789477

Submitted Date: November 18, 2010 (v12)

Study Identification

Unique Protocol ID:	VGFT-OD-0706
Brief Title:	DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)
Official Title:	A Double-Masked, Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap-Eye in Patients With Diabetic Macular Edema (DME)
Secondary IDs:	

Study Status

Record Verification:	November 2010
Overall Status:	Active, not recruiting
Study Start:	December 2008
Primary Completion:	February 2010 [Anticipated]
Study Completion:	February 2011 [Anticipated]
First Submitted:	November 7, 2008
First Submitted that Met QC Criteria:	November 7, 2008
First Posted:	November 11, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	November 18, 2010
Last Update Posted:	November 19, 2010 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals

Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary:	This is a Phase 2, doubled-masked, randomized study of the efficacy and safety of VEGF Trap-Eye in subjects with diabetic macular edema. Approximately 200 subjects will be randomized in the US, Canada, Australia and EU.
Detailed Description:	Qualified subjects will be randomized to one of 5 treatment arms. The active (treatment) phase of the study will be 52 weeks, with a 6 month safety follow-up

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Interventional Study Model:	Parallel Assignment
Number of Arms:	5
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation:	Randomized
Enrollment:	200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 Dose 1	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 2 Dose 2	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 3 Dose 3	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 4 Dose 4	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Active Comparator: 5 Non-drug comparator	Procedure: Non-drug intervention laser every 16 weeks as needed Other Names: • laser photocoagulation

Outcome Measures

Primary Outcome Measures:

1. Change in best corrected visual acuity
   Week 24

Secondary Outcome Measures:

2. Change from baseline in foveal thickness
   Weeks 24 and 52

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Patients with clinically significant DME with central involvement
- Adults 18 years or older with type 1 or 2 diabetes mellitus with diabetic macular edema
- ETDRS BCVA: 20/40 to 20/320 (letter score of 73 to 24) in the study eye

Exclusion Criteria:

- History of vitreoretinal surgery in the study eye
- Panretinal laser photocoagulation or macular laser photocoagulation in the study eye within 3 months of screening
- Previous use of intraocular or periocular corticosteroids in the study eye within 3 months of screening
- Previous treatment with anti-angiogenic drugs in either eye (pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc) within 3 months of screening
- Uncontrolled diabetes mellitus
- Uncontrolled hypertension defined as systolic > 180mmHg or > 160 mmHg on 2 consecutive measurements or diastolic > 100 mmHg on optimal medical regimen
- Ocular disorders in the study eye, other than DME, that may confound interpretation of study results

Contacts/Locations

Study Officials: Robert L Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, California**

Artesia, California, United States, 90701

Beverly Hills, California, United States, 90211

Mountain View, California, United States, 94040

Pasadena, California, United States, 91105

Sacramento, California, United States, 95819

Santa Ana, California, United States, 92705

United States, Connecticut

Hamden, Connecticut, United States, 06518

New London, Connecticut, United States, 06320

United States, Florida

Boynton Beach, Florida, United States, 33426

Fort Lauderdale, Florida, United States, 33334

Fort Myers, Florida, United States, 33912

Ocala, Florida, United States, 34474

Palm Beach Gardens, Florida, United States, 33410

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Hawaii

Honolulu, Hawaii, United States, 96815

United States, Indiana

Indianapolis, Indiana, United States, 46280

United States, Maine

Bangor, Maine, United States, 04401

United States, Maryland

Baltimore, Maryland, United States, 21287

United States, Massachusetts

Boston, Massachusetts, United States, 02114

United States, Michigan

Jackson, Michigan, United States, 48104

United States, Missouri

Kansas City, Missouri, United States, 64108

United States, Nebraska

Lincoln, Nebraska, United States, 68506

United States, New Jersey

New Brunswick, New Jersey, United States, 08901

Northfield, New Jersey, United States, 08225

Toms River, New Jersey, United States, 08753

United States, New York

Rochester, New York, United States, 14620

United States, North Carolina

Charlotte, North Carolina, United States, 28210

Raleigh, North Carolina, United States, 27607

United States, Ohio

Cincinnati, Ohio, United States, 45243

United States, Pennsylvania

Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

Greenville, South Carolina, United States, 29605

West Columbia, South Carolina, United States, 29169

United States, Tennessee

Nashville, Tennessee, United States, 37203

United States, Texas

Abilene, Texas, United States, 79606

Arlington, Texas, United States, 76012

Austin, Texas, United States, 78705

Houston, Texas, United States, 77030

McAllen, Texas, United States, 78503

San Antonio, Texas, United States, 78215

San Antonio, Texas, United States, 78240

United States, Utah

Salt Lake City, Utah, United States, 84107

Austria

Wien, Austria, 1090

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z 3N9

Victoria, British Columbia, Canada, V8V 4X3

Canada, Ontario

London, Ontario, Canada, N6A 4G5

Mississauga, Ontario, Canada, L4W 1W9

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

Regeneron Ex. 2001
Fresenius v. Regeneron
IPR2025-01269
Page 2969 of 3000

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00789477

DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)

Latest version (submitted August 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	November 7, 2008	None (earliest Version on record)
2	○	○	December 5, 2008	Recruitment Status, Arms and Interventions, Contacts/Locations, Study Status, Outcome Measures, Oversight, Eligibility and Study Identification
3	○	○	February 5, 2009	Contacts/Locations, Study Status and Study Identification

Version	A	B	Submitted Date	Changes
4	○	○	February 11, 2009	Contacts/Locations, Study Status and Study Identification
5	○	○	February 13, 2009	Study Identification, Contacts/Locations and Study Status
6	○	○	March 12, 2009	Study Status and Contacts/Locations
7	○	○	April 24, 2009	Contacts/Locations and Study Status
8	○	○	May 27, 2009	Study Status and Contacts/Locations
9	○	○	June 2, 2009	Contacts/Locations and Study Status
10	○	○	June 18, 2009	Contacts/Locations and Study Status
11	◉	◉	July 14, 2009	Recruitment Status, Study Status and Contacts/Locations
12	○	○	November 18, 2010	Study Status
13	○	○	January 24, 2011	Recruitment Status, Study Status and Study Design
14	○	○	May 2, 2011	Study Status, Arms and Interventions
15	○	○	September 27, 2013	Sponsor/Collaborators and Study Status
16	○	○	August 13, 2014	Study Status
17	○	○	August 28, 2014	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Contacts/Locations, Study Design, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00789477

Submitted Date: July 14, 2009 (v11)

Study Identification

Unique Protocol ID: VGFT-OD-0706

Brief Title: DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)

Official Title: A Double-Masked, Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap-Eye in Patients With Diabetic Macular Edema (DME)

Secondary IDs:

Study Status

Record Verification: July 2009

Overall Status: Active, not recruiting

Study Start: December 2008

Primary Completion: February 2010 [Anticipated]

Study Completion: February 2011 [Anticipated]

First Submitted: November 7, 2008

First Submitted that Met QC Criteria: November 7, 2008

First Posted: November 11, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: July 14, 2009

Last Update Posted: July 15, 2009 [Estimate]

Sponsor/Collaborators

Sponsor: Regeneron Pharmaceuticals

Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary:	This is a Phase 2, doubled-masked, randomized study of the efficacy and safety of VEGF Trap-Eye in subjects with diabetic macular edema. Approximately 200 subjects will be randomized in the US, Canada, Australia and EU.
Detailed Description:	Qualified subjects will be randomized to one of 5 treatment arms. The active (treatment) phase of the study will be 52 weeks, with a 6 month safety follow-up

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Interventional Study Model:	Parallel Assignment
Number of Arms:	5
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation:	Randomized
Enrollment:	200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 Dose 1	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 2 Dose 2	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 3 Dose 3	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 4 Dose 4	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Active Comparator: 5 Non-drug comparator	Procedure: Non-drug intervention laser every 16 weeks as needed Other Names: • laser photocoagulation

Outcome Measures

Primary Outcome Measures:

1. Change in best corrected visual acuity
   Week 24

Secondary Outcome Measures:

2. Change from baseline in foveal thickness
   Weeks 24 and 52

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Patients with clinically significant DME with central involvement
- Adults 18 years or older with type 1 or 2 diabetes mellitus with diabetic macular edema
- ETDRS BCVA: 20/40 to 20/320 (letter score of 73 to 24) in the study eye

Exclusion Criteria:

- History of vitreoretinal surgery in the study eye
- Panretinal laser photocoagulation or macular laser photocoagulation in the study eye within 3 months of screening
- Previous use of intraocular or periocular corticosteroids in the study eye within 3 months of screening
- Previous treatment with anti-angiogenic drugs in either eye (pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc) within 3 months of screening
- Uncontrolled diabetes mellitus
- Uncontrolled hypertension defined as systolic > 180mmHg or > 160 mmHg on 2 consecutive measurements or diastolic > 100 mmHg on optimal medical regimen
- Ocular disorders in the study eye, other than DME, that may confound interpretation of study results

Contacts/Locations

Study Officials: Robert L Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, California**

Artesia, California, United States, 90701

Beverly Hills, California, United States, 90211

Mountain View, California, United States, 94040

Pasadena, California, United States, 91105

Sacramento, California, United States, 95819

Santa Ana, California, United States, 92705

United States, Connecticut

Hamden, Connecticut, United States, 06518

New London, Connecticut, United States, 06320

United States, Florida

Boynton Beach, Florida, United States, 33426

Fort Lauderdale, Florida, United States, 33334

Fort Myers, Florida, United States, 33912

Ocala, Florida, United States, 34474

Palm Beach Gardens, Florida, United States, 33410

Winter Haven, Florida, United States, 33880

United States, Georgia

Augusta, Georgia, United States, 30909

United States, Hawaii

Honolulu, Hawaii, United States, 96815

United States, Indiana

Indianapolis, Indiana, United States, 46280

United States, Maine

Bangor, Maine, United States, 04401

United States, Maryland

Baltimore, Maryland, United States, 21287

United States, Massachusetts

Boston, Massachusetts, United States, 02114

United States, Michigan

Jackson, Michigan, United States, 48104

United States, Missouri

Kansas City, Missouri, United States, 64108

United States, Nebraska

Lincoln, Nebraska, United States, 68506

United States, New Jersey

New Brunswick, New Jersey, United States, 08901

Northfield, New Jersey, United States, 08225

Toms River, New Jersey, United States, 08753

United States, New York

Rochester, New York, United States, 14620

United States, North Carolina

Charlotte, North Carolina, United States, 28210

Raleigh, North Carolina, United States, 27607

United States, Ohio

Cincinnati, Ohio, United States, 45243

United States, Pennsylvania

Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

Greenville, South Carolina, United States, 29605

West Columbia, South Carolina, United States, 29169

United States, Tennessee

Nashville, Tennessee, United States, 37203

United States, Texas

Abilene, Texas, United States, 79606

Arlington, Texas, United States, 76012

Austin, Texas, United States, 78705

Houston, Texas, United States, 77030

McAllen, Texas, United States, 78503

San Antonio, Texas, United States, 78215

San Antonio, Texas, United States, 78240

United States, Utah

Salt Lake City, Utah, United States, 84107

Austria

Wien, Austria, 1090

Canada, British Columbia

Vancouver, British Columbia, Canada, V5Z 3N9

Victoria, British Columbia, Canada, V8V 4X3

Canada, Ontario

London, Ontario, Canada, N6A 4G5

Mississauga, Ontario, Canada, L4W 1W9

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

Regeneron Ex. 2001
Fresenius v. Regeneron
IPR2025-01269
Page 2979 of 3000

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00789477

DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)

Latest version (submitted August 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	November 7, 2008	None (earliest Version on record)
2	○	○	December 5, 2008	Recruitment Status, Arms and Interventions, Contacts/Locations, Study Status, Outcome Measures, Oversight, Eligibility and Study Identification
3	○	○	February 5, 2009	Contacts/Locations, Study Status and Study Identification

Version	A	B	Submitted Date	Changes
4	○	○	February 11, 2009	Contacts/Locations, Study Status and Study Identification
5	○	○	February 13, 2009	Study Identification, Contacts/Locations and Study Status
6	○	○	March 12, 2009	Study Status and Contacts/Locations
7	○	○	April 24, 2009	Contacts/Locations and Study Status
8	○	○	May 27, 2009	Study Status and Contacts/Locations
9	○	○	June 2, 2009	Contacts/Locations and Study Status
10	◉	◉	June 18, 2009	Contacts/Locations and Study Status
11	○	○	July 14, 2009	Recruitment Status, Study Status and Contacts/Locations
12	○	○	November 18, 2010	Study Status
13	○	○	January 24, 2011	Recruitment Status, Study Status and Study Design
14	○	○	May 2, 2011	Study Status, Arms and Interventions
15	○	○	September 27, 2013	Sponsor/Collaborators and Study Status
16	○	○	August 13, 2014	Study Status
17	○	○	August 28, 2014	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Contacts/Locations, Study Design, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT00789477

Submitted Date: June 18, 2009 (v10)

Study Identification

Unique Protocol ID: VGFT-OD-0706

Brief Title: DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)

Official Title: A Double-Masked, Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap-Eye in Patients With Diabetic Macular Edema (DME)

Secondary IDs:

Study Status

Record Verification: June 2009

Overall Status: Recruiting

Study Start: December 2008

Primary Completion: February 2010 [Anticipated]

Study Completion: February 2011 [Anticipated]

First Submitted: November 7, 2008

First Submitted that Met QC Criteria: November 7, 2008

First Posted: November 11, 2008 [Estimate]

Last Update Submitted that Met QC Criteria: June 18, 2009

Last Update Posted: June 19, 2009 [Estimate]

Sponsor/Collaborators

Sponsor: Regeneron Pharmaceuticals

Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary:	This is a Phase 2, doubled-masked, randomized study of the efficacy and safety of VEGF Trap-Eye in subjects with diabetic macular edema. Approximately 200 subjects will be randomized in the US, Canada, Australia and EU.
Detailed Description:	Qualified subjects will be randomized to one of 5 treatment arms. The active (treatment) phase of the study will be 52 weeks, with a 6 month safety follow-up

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Interventional Study Model:	Parallel Assignment
Number of Arms:	5
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation:	Randomized
Enrollment:	200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 Dose 1	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 2 Dose 2	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 3 Dose 3	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 4 Dose 4	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Active Comparator: 5 Non-drug comparator	Procedure: Non-drug intervention laser every 16 weeks as needed Other Names: • laser photocoagulation

Outcome Measures

Primary Outcome Measures:

1. Change in best corrected visual acuity
   Week 24

Secondary Outcome Measures:

2. Change from baseline in foveal thickness
   Weeks 24 and 52

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Patients with clinically significant DME with central involvement
- Adults 18 years or older with type 1 or 2 diabetes mellitus with diabetic macular edema
- ETDRS BCVA: 20/40 to 20/320 (letter score of 73 to 24) in the study eye

Exclusion Criteria:

- History of vitreoretinal surgery in the study eye
- Panretinal laser photocoagulation or macular laser photocoagulation in the study eye within 3 months of screening
- Previous use of intraocular or periocular corticosteroids in the study eye within 3 months of screening
- Previous treatment with anti-angiogenic drugs in either eye (pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc) within 3 months of screening
- Uncontrolled diabetes mellitus
- Uncontrolled hypertension defined as systolic > 180mmHg or > 160 mmHg on 2 consecutive measurements or diastolic > 100 mmHg on optimal medical regimen
- Ocular disorders in the study eye, other than DME, that may confound interpretation of study results

Contacts/Locations

Central Contact: Maria Thurman
Telephone: 919-294-5075
Email: maria.thurman@parexel.com

Study Officials: Robert L Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, California**

[Recruiting]
Artesia, California, United States, 90701

[Recruiting]

Beverly Hills, California, United States, 90211

[Recruiting]

Mountain View, California, United States, 94040

[Recruiting]

Pasadena, California, United States, 91105

[Recruiting]

Sacramento, California, United States, 95819

[Recruiting]

Santa Ana, California, United States, 92705

United States, Connecticut

[Recruiting]

Hamden, Connecticut, United States, 06518

[Recruiting]

New London, Connecticut, United States, 06320

United States, Florida

[Recruiting]

Boynton Beach, Florida, United States, 33426

[Recruiting]

Fort Lauderdale, Florida, United States, 33334

[Recruiting]

Fort Myers, Florida, United States, 33912

[Recruiting]

Ocala, Florida, United States, 34474

[Recruiting]

Palm Beach Gardens, Florida, United States, 33410

[Recruiting]

Winter Haven, Florida, United States, 33880

United States, Georgia

[Recruiting]

Augusta, Georgia, United States, 30909

United States, Hawaii

[Terminated]

Honolulu, Hawaii, United States, 96815

United States, Indiana

[Recruiting]

Indianapolis, Indiana, United States, 46280

United States, Maine

[Recruiting]

Bangor, Maine, United States, 04401

United States, Maryland

[Recruiting]

Baltimore, Maryland, United States, 21287

United States, Massachusetts

[Recruiting]

Boston, Massachusetts, United States, 02114

United States, Michigan

[Recruiting]

Jackson, Michigan, United States, 48104

United States, Missouri

[Recruiting]

Kansas City, Missouri, United States, 64108

United States, Nebraska

[Recruiting]

Lincoln, Nebraska, United States, 68506

United States, New Jersey

[Recruiting]
New Brunswick, New Jersey, United States, 08901

[Recruiting]
Northfield, New Jersey, United States, 08225

[Recruiting]
Toms River, New Jersey, United States, 08753

United States, New York

[Recruiting]
Rochester, New York, United States, 14620

United States, North Carolina

[Recruiting]
Charlotte, North Carolina, United States, 28210

[Recruiting]
Raleigh, North Carolina, United States, 27607

United States, Ohio

[Recruiting]
Cincinnati, Ohio, United States, 45243

United States, Pennsylvania

[Recruiting]
Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

[Terminated]
Greenville, South Carolina, United States, 29605

[Recruiting]
West Columbia, South Carolina, United States, 29169

United States, Tennessee

[Recruiting]

Nashville, Tennessee, United States, 37203

United States, Texas

[Recruiting]

Abilene, Texas, United States, 79606

[Recruiting]

Arlington, Texas, United States, 76012

[Recruiting]

Austin, Texas, United States, 78705

[Recruiting]

Houston, Texas, United States, 77030

[Recruiting]

McAllen, Texas, United States, 78503

[Recruiting]

San Antonio, Texas, United States, 78215

[Recruiting]

San Antonio, Texas, United States, 78240

United States, Utah

[Recruiting]

Salt Lake City, Utah, United States, 84107

Austria

[Recruiting]

Wien, Austria, 1090

Canada, British Columbia

[Recruiting]

Vancouver, British Columbia, Canada, V5Z 3N9

[Recruiting]

Victoria, British Columbia, Canada, V8V 4X3

Canada, Ontario

[Recruiting]

London, Ontario, Canada, N6A 4G5

[Recruiting]

Mississauga, Ontario, Canada, L4W 1W9

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Scroll up to access the controls

Scroll to the Study top

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

U.S. National Library of Medicine

ClinicalTrials.gov archive

History of Changes for Study: NCT00789477

DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)

Latest version (submitted August 28, 2014) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in *green*.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	○	○	November 7, 2008	None (earliest Version on record)
2	○	○	December 5, 2008	Recruitment Status, Arms and Interventions, Contacts/Locations, Study Status, Outcome Measures, Oversight, Eligibility and Study Identification
3	○	○	February 5, 2009	Contacts/Locations, Study Status and Study Identification

Version	A	B	Submitted Date	Changes
4	○	○	February 11, 2009	Contacts/Locations, Study Status and Study Identification
5	○	○	February 13, 2009	Study Identification, Contacts/Locations and Study Status
6	○	○	March 12, 2009	Study Status and Contacts/Locations
7	○	○	April 24, 2009	Contacts/Locations and Study Status
8	○	○	May 27, 2009	Study Status and Contacts/Locations
9	◉	◉	June 2, 2009	Contacts/Locations and Study Status
10	○	○	June 18, 2009	Contacts/Locations and Study Status
11	○	○	July 14, 2009	Recruitment Status, Study Status and Contacts/Locations
12	○	○	November 18, 2010	Study Status
13	○	○	January 24, 2011	Recruitment Status, Study Status and Study Design
14	○	○	May 2, 2011	Study Status, Arms and Interventions
15	○	○	September 27, 2013	Sponsor/Collaborators and Study Status
16	○	○	August 13, 2014	Study Status
17	○	○	August 28, 2014	Arms and Interventions, Outcome Measures, Study Status, More Information, Reported Adverse Events, Baseline Characteristics, Participant Flow, Contacts/Locations, Study Design, Study Description and Study Identification

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Study NCT00789477

Submitted Date: June 2, 2009 (v9)

Study Identification

Unique Protocol ID:	VGFT-OD-0706
Brief Title:	DME And VEGF Trap-Eye: INvestigation of Clinical Impact (DA VINCI)
Official Title:	A Double-Masked, Randomized, Controlled Study of the Safety, Tolerability and Biological Effect of Repeated Intravitreal Administration of VEGF Trap-Eye in Patients With Diabetic Macular Edema (DME)
Secondary IDs:	

Study Status

Record Verification:	June 2009
Overall Status:	Recruiting
Study Start:	December 2008
Primary Completion:	February 2010 [Anticipated]
Study Completion:	February 2011 [Anticipated]
First Submitted:	November 7, 2008
First Submitted that Met QC Criteria:	November 7, 2008
First Posted:	November 11, 2008 [Estimate]
Last Update Submitted that Met QC Criteria:	June 2, 2009
Last Update Posted:	June 4, 2009 [Estimate]

Sponsor/Collaborators

Sponsor:	Regeneron Pharmaceuticals

Responsible Party:	
Collaborators:	Bayer

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	No

Study Description

Brief Summary:	This is a Phase 2, doubled-masked, randomized study of the efficacy and safety of VEGF Trap-Eye in subjects with diabetic macular edema. Approximately 200 subjects will be randomized in the US, Canada, Australia and EU.
Detailed Description:	Qualified subjects will be randomized to one of 5 treatment arms. The active (treatment) phase of the study will be 52 weeks, with a 6 month safety follow-up

Conditions

Conditions:	Diabetic Macular Edema
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Interventional Study Model:	Parallel Assignment
Number of Arms:	5
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation:	Randomized
Enrollment:	200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1 Dose 1	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 2 Dose 2	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 3 Dose 3	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Experimental: 4 Dose 4	Biological: VEGF Trap-Eye Intravitreal injection, repeating dose
Active Comparator: 5 Non-drug comparator	Procedure: Non-drug intervention laser every 16 weeks as needed Other Names: • laser photocoagulation

Outcome Measures

Primary Outcome Measures:

1. Change in best corrected visual acuity
   Week 24

Secondary Outcome Measures:

2. Change from baseline in foveal thickness
   Weeks 24 and 52

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

- Patients with clinically significant DME with central involvement
- Adults 18 years or older with type 1 or 2 diabetes mellitus with diabetic macular edema
- ETDRS BCVA: 20/40 to 20/320 (letter score of 73 to 24) in the study eye

Exclusion Criteria:

- History of vitreoretinal surgery in the study eye
- Panretinal laser photocoagulation or macular laser photocoagulation in the study eye within 3 months of screening
- Previous use of intraocular or periocular corticosteroids in the study eye within 3 months of screening
- Previous treatment with anti-angiogenic drugs in either eye (pegaptanib sodium, anecortave acetate, bevacizumab, ranibizumab, etc) within 3 months of screening
- Uncontrolled diabetes mellitus
- Uncontrolled hypertension defined as systolic > 180mmHg or > 160 mmHg on 2 consecutive measurements or diastolic > 100 mmHg on optimal medical regimen
- Ocular disorders in the study eye, other than DME, that may confound interpretation of study results

Contacts/Locations

Central Contact: Maria Thurman
Telephone: 919-294-5075
Email: maria.thurman@parexel.com

Study Officials: Robert L Vitti, MD
Study Director
Regeneron Pharmaceuticals

Locations: **United States, California**

[Recruiting]
Artesia, California, United States, 90701

[Recruiting]

Beverly Hills, California, United States, 90211

[Recruiting]

Mountain View, California, United States, 94040

[Recruiting]

Pasadena, California, United States, 91105

[Recruiting]

Sacramento, California, United States, 95819

[Recruiting]

Santa Ana, California, United States, 92705

United States, Connecticut

[Recruiting]

Hamden, Connecticut, United States, 06518

[Recruiting]

New London, Connecticut, United States, 06320

United States, Florida

[Recruiting]

Boynton Beach, Florida, United States, 33426

[Recruiting]

Fort Lauderdale, Florida, United States, 33334

[Recruiting]

Fort Myers, Florida, United States, 33912

[Recruiting]

Ocala, Florida, United States, 34474

[Recruiting]

Palm Beach Gardens, Florida, United States, 33410

[Recruiting]

Winter Haven, Florida, United States, 33880

United States, Georgia

[Recruiting]

Augusta, Georgia, United States, 30909

United States, Hawaii

[Recruiting]

Honolulu, Hawaii, United States, 96815

United States, Indiana

[Recruiting]

Indianapolis, Indiana, United States, 46280

United States, Maine

[Recruiting]

Bangor, Maine, United States, 04401

United States, Maryland

[Recruiting]

Baltimore, Maryland, United States, 21287

United States, Massachusetts

[Recruiting]

Boston, Massachusetts, United States, 02114

United States, Michigan

[Recruiting]

Jackson, Michigan, United States, 48104

United States, Missouri

[Recruiting]

Kansas City, Missouri, United States, 64108

United States, Nebraska

[Recruiting]

Lincoln, Nebraska, United States, 68506

United States, New Jersey

[Recruiting]
New Brunswick, New Jersey, United States, 08901

[Recruiting]
Northfield, New Jersey, United States, 08225

[Recruiting]
Toms River, New Jersey, United States, 08753

United States, New York

[Recruiting]
Rochester, New York, United States, 14620

United States, North Carolina

[Recruiting]
Charlotte, North Carolina, United States, 28210

[Recruiting]
Raleigh, North Carolina, United States, 27607

United States, Ohio

[Recruiting]
Cincinnati, Ohio, United States, 45243

United States, Pennsylvania

[Recruiting]
Pittsburgh, Pennsylvania, United States, 15213

United States, South Carolina

[Recruiting]
Greenville, South Carolina, United States, 29605

[Recruiting]
West Columbia, South Carolina, United States, 29169

United States, Tennessee

[Recruiting]

Nashville, Tennessee, United States, 37203

United States, Texas

[Recruiting]

Abilene, Texas, United States, 79606

[Recruiting]

Arlington, Texas, United States, 76012

[Recruiting]

Austin, Texas, United States, 78705

[Recruiting]

Houston, Texas, United States, 77030

[Recruiting]

McAllen, Texas, United States, 78503

[Recruiting]

San Antonio, Texas, United States, 78215

[Recruiting]

San Antonio, Texas, United States, 78240

United States, Utah

[Recruiting]

Salt Lake City, Utah, United States, 84107

Canada, British Columbia

[Recruiting]

Vancouver, British Columbia, Canada, V5Z 3N9

[Recruiting]

Victoria, British Columbia, Canada, V8V 4X3

Canada, Ontario

[Recruiting]

London, Ontario, Canada, N6A 4G5